

Optimizing Access Surgery In Senior haemodialysis patients (OASIS): Statistical Analysis Plan (SAP)



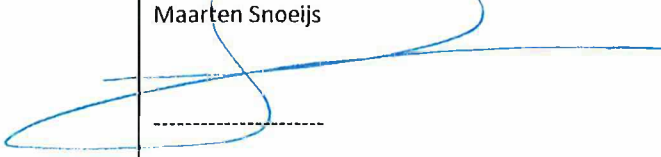
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1. Introduction

1.1. Background and rationale

The haemodialysis population has been growing older and older over the past decades(1). These patients need a reliable vascular access to receive haemodialysis treatment. Vascular access related complications are a major determinant of the quality of life and health care costs for these vulnerable patients. The three different types of vascular access, i.e. autologous arteriovenous fistulas (AVFs), arteriovenous grafts (AVGs), and central venous catheters (CVCs), have never been compared in elderly patients in randomized controlled trials.

1.2. Objectives

The OASIS research project aims to determine the optimal surgical strategy for vascular access creation in elderly haemodialysis patients with limited life expectancy. In current clinical practice AVFs in the arm are usually preferred regardless of patient age(2). By randomizing elderly patients, the OASIS study aims to determine if AVGs or permanent CVCs result in less access-related interventions, better quality of life, and reduced costs as compared to creation of AVFs.

2. Study Methods

2.1. Trial design

This is a parallel group, open-label, multicentre randomized controlled clinical trial with a superiority framework and a 1:1:1 individual participant treatment allocation ratio over 3 study arms with different surgical strategies for vascular access creation. The trial has a variable follow-up design in which all participants will remain in the study until trial closeout at the time when the last patient enrolled has contributed one year of follow-up.

2.2. Randomization

Patients will be randomized using a 1:1:1 individual participant treatment allocation ratio. The independent data management centre will generate the treatment allocation sequence by a random number producing algorithm on a computer. We will use block randomization with randomly varying block sizes of 3 and 6 to ensure equal numbers of participants in each treatment arm and to keep the investigators unaware of the next treatment assignment. Randomization will be stratified by treatment centre. The local investigators will enrol participants and will be informed of treatment assignment through a web-based service provided by the data management centre.

2.3. Sample size

Sample sizes were estimated for the number of access-related interventions required for each person-year of dialysis treatment (i.e. the primary outcome), which will be analysed using a general linear model with Poisson distribution and time as off-set variable. Since two intervention groups will be compared to the control group, we used Bonferroni correction to account for multiple comparisons, which resulted in an alpha of 0.025. The clinically relevant effect size was considered to be 1 percutaneous intervention per year and 0.5 surgical interventions per year. Since these interventions occur at a ratio of 1:0.7 a reduction of the overall intervention rate by 0.80 interventions per year was used as the clinically relevant effect for sample size calculations. The average number of interventions per year in the control group of autologous arteriovenous fistula creation was

taken from the systematic review of the literature at 2.48 interventions per year(3). With these assumptions, a total number of 195 patients (65 in each treatment arm) with one year of follow-up achieves 80% power to detect a 0.80 decrease in the average number of access-related interventions per person-year of haemodialysis treatment between the intervention groups (arteriovenous graft placement and central venous catheter insertion) and the control group (autologous arteriovenous fistula creation; event rate 2.48 interventions per year) using a two-sided, large-samples z-test of the Poisson event-rate difference at a significance level of 0.025. Since the study includes haemodialysis patients with a limited life expectancy, a substantial proportion of patients are expected to die before contributing one year of follow-up. To compensate for the resulting loss of statistical power, we have adopted a variable follow-up design with trial closeout at the time when the last patient enrolled has one year of follow-up. Since participant recruitment is expected to take 1.75 years, patients who are enrolled early in the project may contribute almost three years of follow-up time. The resulting additional follow-up time will more than compensate for the loss of follow-up due to patient mortality in the first year of the study period.

Due to slow enrolment, follow-up time per participant is much longer than anticipated at trial initiation. After enrolment of 165 participants, calculations based on actual event and mortality rates showed that the trial had sufficient statistical power to detect a relative difference in event rate of 0.67, corresponding to an absolute difference below the minimal clinically relevant difference of 0.80 access-related interventions per year. Therefore, enrolment was closed at 165 participants and follow-up was ended for all participants at 31-03-2026.

2.4. Framework

A superiority framework will be used. Both intervention groups (arteriovenous graft and central venous catheter placement) will be compared to the control group of autologous arteriovenous fistula creation. The sample size estimates for the trial have been adjusted for this double comparison. Every effort is made to establish eligibility of participants prior to randomization; no withdrawals due to ineligibility are allowed and the analyses include all participants enrolled. Non-adherence to the allocated treatment group is expected as patients cross over to another surgical strategy for vascular access. Non-adherence is minimized by recommending efforts to continue treatment as randomized when confronted with adverse events. The primary analysis will be on the intention to treat population (i.e. no participants are withdrawn from analysis for lack of adherence to treatment allocation); exploratory on-treatment analyses will be performed. Exploratory analyses will be done with adjustment for Dusseux risk score and frailty scores including interaction terms with the treatment group. The primary outcome will also be analysed with major interventions having twice the weight of minor interventions and for different phases of the vascular access life cycle. Subgroup analyses will be done for patients who had already started haemodialysis treatment with a temporary central venous catheter at enrolment and for centres with aggressive versus conservative strategies with regards to vascular access surveillance and pre-emptive correction of access stenosis. Every effort is made to avoid missing data, which specifically includes assistance from dialysis nurses in obtaining patient-reported outcome measures during dialysis sessions. Primary outcome data are not expected to be missing, as interventions on vascular access will be reported in the patients' medical files. We expect no loss to follow-up in the study participants since they are observed three times per week in the dialysis unit. Patient-reported outcome measures will be analysed using generalized estimating equations that allow for missing data. Other missing data will be handled by using 10 imputation cycles with regression methods, performing standard analyses for each imputation cycle, and considering the variability across the imputation cycles in the final analysis. Outliers will not be removed from the analysis unless the data can clearly be shown to be erroneous.

2.5. Interim analyses and stopping guidance

2.5.1. Statistical interim analyses and stopping guidance

During the study several interim analyses will be performed. The members of the Data Safety Monitoring Board (DSMB) and the study coordinator will meet at predefined intervals based on the number of enrolments and at least once every six months. The task and responsibility of the DSMB is to do interim safety analyses when 50, 100, and 150 patients have been randomized and followed up for at least 6 months. These interim analyses are for safety only (i.e. access-related serious adverse events and mortality) and not for early stopping for efficacy. Significant differences on safety outcomes may lead to discontinuation of the trial as recommended by the DSMB. The members of the DSMB are not involved with the trial in any other way and have no competing interests.

2.5.2. Planned adjustments

The interim analyses are for safety only and no adjustments are planned based on the interim analyses results.

2.5.3. Guidelines for stopping the trial early

The number of access-related adverse events (AEs), serious adverse events (SAEs) per person-year will be analysed using general linear models with Poisson distribution, and mortality will be analysed using Cox regression. Statistically significant differences between treatment groups will be used as a guideline to issue recommendations by the DSMB. Reasons to disregard a statistically significant difference between treatment groups by the DSMB will be recorded. More weight will be given to mortality than to access-related serious adverse events. Significant differences on safety outcomes may lead to discontinuation of the trial as recommended by the data safety monitoring board.

2.6. Timing of final analysis

All results will be analysed at the end of the study. The trial has a variable follow-up design in which all participants will remain in the study until trial closeout, one year after inclusion of the last patient.

2.7. Timing of outcome assessments

All potential participants will have a duplex ultrasound of arteries and veins in the arms as part of standard clinical care when referred for vascular access creation. Duplex ultrasound of the internal jugular veins should be performed in patients with a history of previous central venous catheters, a deep venous thrombosis of the arm, an operation or radiation therapy in the head neck area, to assess the patency of the veins. After informed consent, randomization and treatment assignment, patients will have a vascular access created according to standard clinical practice. Study endpoints will be assessed using data that are routinely recorded in electronic patient files and using patient-reported outcome measure and cost questionnaires. Subjects enrolled in the trial will be asked to fill out questionnaires (SF-12/DSI, SF-VAQ, EQ-5D-5L and MCQ) at baseline and every 3 months during the first year of the study and during the first year after dialysis initiation.

3. Statistical Principles

3.1. General principles

Descriptive analyses will be reported using summary tables and figures. Continuous variables will be summarized with counts, means, standard deviations, medians, confidence intervals, minimums, and maximums were appropriate. Categorical variables will be reported by counts and percentages. Formal inferential statistical analyses techniques will be discussed in subsequent sections of this SAP. P-values <0.05 are considered

statistically significant, unless otherwise stated in the SAP. 95% confidence intervals around estimates will be reported, unless otherwise stated in the SAP. Analyses and tabulations will be performed using R (R-Project) or SPSS (IBM). All reported output will undergo a senior level statistical review to ensure valid methods were used, and that all data manipulations and calculations are correct and consistent with the SAP. Upon completion of the analysis, the analyses code will be collected and filed. Missing or invalid data will be treated as missing data, unless otherwise stated.

3.2. Adherence and protocol deviations

3.2.1. Definition of adherence

Every effort is made to establish eligibility of participants prior to randomization; no withdrawals due to ineligibility are allowed and the analyses include all participants enrolled. Non-adherence to the allocated treatment group is expected as patients cross over to another surgical strategy for vascular access. Non-adherence is minimized by recommending efforts to continue treatment as randomized when confronted with adverse events.

3.2.2. Description of presenting adherence

The primary analysis will be on the intention to treat population (i.e. no participants are withdrawn from analysis for lack of adherence to treatment allocation); exploratory per protocol analyses will also be performed. Treatment non-adherence and crossovers, stratified by the randomized type of vascular access will be presented in a table. Patients were considered non-adherent if they received a vascular access type different from the allocated type after having received the allocated access. Patients were considered crossovers if they received a vascular access type different from the allocated type without ever receiving the allocated access. Results will be reported as incidence rate ratios with 97.5% confidence intervals and corresponding two-sided p-values. Patients who withdrew from the study prior to undergoing the assigned vascular access procedure will be reported separately.

3.2.3. Definition of protocol deviations

We will register study protocol violations during the enrolment and follow-up phase. Our analysis will focus on protocol deviations with a potential impact on the study results. We will investigate such cases, including crossovers and non-adherence to the assigned treatment, by interviewing the treating physician. To minimize crossovers and non-adherence, eligibility will be confirmed prior to randomization. After allocation, efforts will be made to adhere to the assigned treatment strategy, including in the presence of adverse events. If the allocated vascular access strategy is not feasible, switching to an alternative strategy is permitted at the discretion of the vascular access team in consultation with the project leader. Such cases will not be considered protocol deviations. Non-adherence or crossover without reasonable efforts to continue the allocated strategy or without prior consultation with the vascular access team and project leader will be classified as protocol violations. The use of a temporary central venous catheter will not be considered a treatment group crossover.

3.2.4. Description of which protocol deviations will be summarized

All protocol deviations are listed during the follow up. The protocol deviations that possibly influenced the final outcome will be mentioned in the discussion.

4. Trial Population

4.1. Screening data

All patients aged 70 years or older referred for vascular access creation will be screened, and those not included in the clinical trial were recorded in a screening log. Following a protocol amendment effective September 1, 2023, the screening criteria were expanded to include patients aged 65 years or older; from that time onward, all non-included patients aged 65 years or older were recorded in the screening log. The following data will be obtained and reported in a table to describe the representativeness of the study population sample: Age, sex, comorbidities, primary kidney disease and dialysis status (Table 2B).

4.2. Eligibility

Patients of 65 years or older who are expected to start haemodialysis treatment within 6 months or who have started haemodialysis treatment with a catheter in the past 6 months. Patients with an exceptionally long life expectancy (Dusseux risk score <5; 33% of this population) will be excluded from the trial(4). Only patients with suitable vascular anatomy for all types of vascular access based on duplex ultrasound will be included in the trial. Duplex ultrasound examination of the arms is part of standard clinical care when patients are referred for vascular access creation.

4.2.1. Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Adult patients aged 65 years or older;
2. End-stage renal disease with unlikely recovery of kidney function according to the attending nephrologist;
3. Haemodialysis is the intended long-term modality of treatment for end-stage renal disease;
4. Fit for vascular access surgery as determined by the local multidisciplinary vascular access team;
5.
 - a. Expected to start haemodialysis treatment within 6 months at the time of treatment assignment; or
 - b. Treated with haemodialysis for 6 months or less at the time of treatment assignment using a tunnelled or non-tunnelled central venous catheter for vascular access;
6. Planning to remain in one of participating dialysis centres for at least 1 year;
7. Suitable vascular anatomy for all types of vascular access based on duplex ultrasound of the arms, defined as:
 - at least one suitable configuration for an arteriovenous fistula using minimal arterial and venous diameters of 2mm for radiocephalic fistulas and 3mm for brachiocephalic and brachiobasilic fistulas;
 - at least one suitable configuration for an arteriovenous graft using minimal arterial and venous diameters of 3mm and 4mm, respectively; and
 - at least one open internal jugular vein for a central venous catheter. For patients without any history of previous central venous catheters, a deep venous thrombosis of the arm, an operation or radiation therapy in the head neck area, it may be assumed that at least one of the internal jugular veins is open. Patients with one or more of the before mentioned risk factors will receive a duplex ultrasound of the jugular veins to assess the patency.

4.2.2. Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Patent arteriovenous fistula or graft already in place;
2. Prior unsuccessful arteriovenous fistula or graft vascular access surgery;
3. Kidney transplantation planned within 6 months;
4. Metastatic malignancies or other condition associated with a life expectancy of <6 months, in the opinion of the attending nephrologist;
5. Unable to provide informed consent;
6. Dusseux risk score <5, indicating an unusually long life expectancy for elderly patients starting haemodialysis treatment (see Figure 1).

Dusseux risk score(4)

An external validation of the Dusseux mortality prediction score for elderly haemodialysis patients was performed, in order to determine the predictive performance in a Dutch cohort and to determine an appropriate cut-off point for patient inclusion in the OASIS trial. The prediction score was validated in the NECOSAD (Netherlands Cooperative Study on the Adequacy of Dialysis) multicentre, prospective cohort study, in which 38 dialysis centres throughout the Netherlands participated. Adult incident dialysis patients were included at the start of dialysis treatment if they had no history of previous renal replacement therapy. Patients were followed until the time of death or censored due to kidney transplantation or loss to follow-up. Inclusion of patients took place between 1997 and 2007 and follow-up data on death was available until February 1, 2015. The analysis was restricted to haemodialysis patients aged 70 years and older. A cut-off between 4 and 5 points resulted in a low-risk group (22% of the population) with a median life expectancy of approximately 5 years and a high-risk group (78% of the population) with a median life expectancy of approximately 2 years (see Figure 1). We added an additional age category to the Dusseux risk score in order to allow enrolment of patients between 65 and 70 years. When this age category was assigned -3 points, median survival in the high-risk and low-risk groups was comparable to patients of 70 years or older (2.2 vs 2.1 years for the high-risk groups and 4.4 vs 4.4 years for the low-risk groups). In the additional age category of 65-69 years, 39% of patients are in the high-risk group and 61% are in the low-risk group.

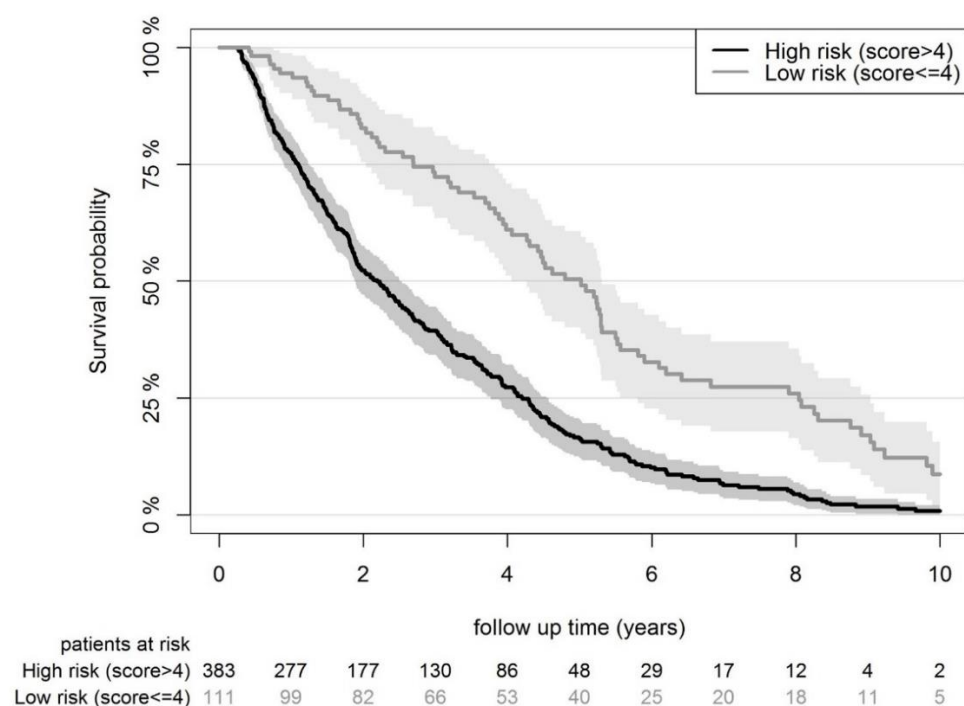


Figure 1 - Performance of Dusseux risk score in Dutch NECOSAD database

4.3. Recruitment

Recruitment information will be presented using a flow diagram according the CONSORT statement for interventional studies(5). The recruitment and informed consent procedures are described in the main protocol section 11.2. The flow diagram will contain information on numbers of patients included in the study and screen failures. Reasons for nonparticipation are provided for each stage.

4.4. Withdrawal/follow up

4.4.1. Level of withdrawal

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

4.4.2. Timing of withdrawal

Patients who decided to leave the study or who have been withdrawn from the study for medical reasons will not be replaced. Data collected for the study will be used until the patient has withdrawn from the study. Patients who discontinue haemodialysis treatment after kidney transplantation, peritoneal dialysis, recovery of renal function, or refusal of further haemodialysis will remain in the trial. Patients who decided to leave the study or who have been withdrawn from the study for medical reasons will receive standard medical care.

4.4.3. Reasons and details of presented data

We expect no loss to follow-up in the study participants since they are observed three times per week in the dialysis unit. The amount of patients and their different reasons for withdrawal will be presented in a flow chart.

4.5. Interim Analysis population

Interim safety analyses will be done when 50, 100, 150, and 195 patients have been randomized and followed up for 6 months. All patients who were enrolled and randomized in the trial at the time of the interim analysis will be analysed.

4.6. Final analysis population

All patients who were enrolled and randomized in the trial.

4.7. Baseline patient characteristics

Baseline characteristics will include age (years), sex (male/female), primary kidney disease, body height (cm), body weight (kg), Clinical Frailty Scale score, medical history, medication use, previous or current renal replacement therapy (using a temporary CVC), duplex ultrasound findings, mobility score, biochemical parameters, and smoking status.

4.8. Details of how baseline characteristics will be descriptively summarized

Baseline characteristics will be presented in a table by treatment arm after the initial randomization. Means and standard deviations (SDs) will be used to report continuous variables, and median and interquartile ranges (IQR) to report categorical values. (See tables and figures – Section 1)

5. Analysis

5.1. Outcome definitions

5.1.1. Primary outcome

The primary outcome will be defined as the number of access-related interventions required for each person-year of haemodialysis treatment. The primary outcome corresponds to the recently proposed core outcome measure for haemodialysis vascular access. This outcome measure includes all percutaneous access interventions (including central venous catheter placement, removal and guidewire exchange, angioplasty, stent placement, and percutaneous thrombectomy) and surgical access procedures (including initial access creation, subsequent access placements if the first access failed, and surgical revisions to promote maturation or maintain long-term patency, including open thrombectomy) from randomization and treatment assignment until the end of the study period or death. The outcome measure specifically includes interventions before dialysis initiation and after dialysis cessation in the occasional patient who stops haemodialysis treatment after kidney transplantation, peritoneal dialysis, recovery of renal function, or refusal of further haemodialysis. Patients who discontinue haemodialysis treatment will therefore remain in the trial. Access-related complications that are resolved using conservative or pharmacological treatment are not considered as interventions. Interventions that are done under general anaesthesia or that require hospital admission of more than one day are scored as major interventions, whereas interventions under local or locoregional anaesthesia as day-case or office procedures are scored as minor interventions. Interventions will also be classified according to the phase in the vascular access life cycle, i.e. maturation (vascular access creation until functional), functional (functional until vascular access abandonment), next access (after abandonment of previous access), to gain more insight into potential differences between study groups.

5.1.2. Secondary outcomes

1. Patient-reported outcome measures (questionnaires administered during haemodialysis sessions in the following order).
 - I. Short Form Health Survey (SF-12) / Dialysis Symptom Index (DSI) measured at baseline and every 3 months during the first year of the study and during the first year after dialysis initiation. Nefrovisie has included patient-reported outcome measures as a standard item in the Dutch national patient registry. The questionnaires include the physical and mental summary scales of the generic SF-12 and the DSI to measure generic health related quality of life as well as disease-specific symptom burden. We will use these questionnaires that have already been implemented in standard clinical care as a secondary outcome in our trial. SF-12 item scores will be linearly transformed to a 0–100 scale, with 0 indicating the worst and 100 the best possible health status. Transformed score = $((\text{observed score} - \text{lowest possible score}) / (\text{score range})) \times 100$. Total DSI scores will be calculated by summing severity scores across all 30 items, the severity is rated on a 5-point Likert scale (usually 0="not at all" to 4="very much", range 0-120). In addition, the mean number of symptoms per patient will be determined (range 0-30 symptoms).
 - II. Short-Form Vascular Access Questionnaire (SF-VAQ) measured every month during the first year of the study and during the first year after dialysis initiation. The SF-VAQ was developed to measure haemodialysis patients' satisfaction with their vascular access. The questionnaire contains 13 items in 4 domains (overall satisfaction, physical symptoms, social functioning, and complications), has a single summary score and takes approximately 10 minutes to administer. The questionnaire has high test-retest reliability and internal consistency. The questionnaire evaluates four domains of patient access satisfaction: overall satisfaction, physical symptoms,

social functioning, and complications. Each item is rated by the patient on a 7-point Likert scale where 7 indicates the highest level of dissatisfaction. Total scores (range 4-28) as well as domain-specific scores will be calculated by summing the item scores within each domain. Scores will also be linearly transformed to a 0–100 scale for interpretability.

- III. 5-level EuroQol 5-dimensional questionnaire (EQ-5D-5L) measured at baseline and every 3 months during the first year of the study and during the first year after dialysis initiation. The EQ-5D-5L was developed to measure health-state utility values. The questionnaire contains self-classifiers in 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and a visual analogue scale and has been used in patients with end-stage renal disease. For the five dimensions, each item is scored from 1 to 5, where 1 indicates no problems in that domain and 5 indicates extreme problems or inability to perform the activity. Both total scores across all five dimensions and scores for each individual dimension are reported. The VAS provides a score from 0 to 100, representing the patient's overall health status, and is reported separately, with higher scores indicating better health.
2. Access-related complications per person-year from the first intervention after treatment assignment until the end of the study period or death.

Access-related complications of Clavien-Dindo grade 2 or higher will be registered. Grade 2 complications require pharmacological treatment including catheter thrombolysis, antibiotics, and blood transfusions. Complications that require no pharmaceutical or interventional treatment (grade 1) are not considered relevant for this clinical trial. Any effect of these complications on quality of life or patient satisfaction will be captured in the patient-reported outcome measures.
 3. Days in hospital from randomization and treatment assignment to the end of the study period or death.
 - I. The number of days admitted to hospital or visiting out-patient clinics for any reason per person-year (including haemodialysis sessions).
 - II. The number of days admitted to hospital or visiting out-patient clinics for vascular access-related reasons per person-year (excluding haemodialysis sessions).
 - III. The number of days admitted to hospital for any reason per person-year.
 - IV. The number of days admitted to hospital for vascular access-related reasons per person-year.
 4. Mortality from randomization and treatment assignment to the end of the study period.
 5. Other outcome measures will be registered for exploratory analyses and are defined according to the ESVS guidelines on vascular access(2):
 - I. Primary patency of vascular access (intervention-free vascular access survival): the interval between vascular access creation and the first re-intervention for vascular access dysfunction or thrombosis or its abandonment.
 - II. Assisted primary patency of vascular access (thrombosis-free vascular access survival): the interval between vascular access creation and the first occlusion or its abandonment.
 - III. Primary functional patency of vascular access: the interval between the first use of a newly created vascular access and the first re-intervention to rescue the vascular access or its abandonment.
 - IV. Secondary patency of vascular access: the interval between vascular access creation and the day on which the vascular access is deemed to be permanently unusable (i.e. access abandonment).
 - V. Time until mature vascular access (definition according to American Society of Nephrology): the interval between vascular access creation and mature vascular access. An arteriovenous fistula is mature when it has a flow volume of >500mL/ min and an internal vein diameter of >5mm. An

arteriovenous graft is mature when it has a flow volume of >500mL/min. A central venous catheter is mature immediately after insertion.

- VI. Time until functional vascular access: the interval between vascular access creation and functional vascular access. An arteriovenous fistula or graft is functional when it has been cannulated successfully with two needles, over a period of at least 6 haemodialysis sessions during a 30-day period, and delivered the prescribed blood flow throughout haemodialysis (usually at least 300mL/min) and achieved adequate haemodialysis dose. A central venous catheter is functional in the absence of peak flow of 200 mL/min or less for 30 minutes during haemodialysis, mean blood flow of 250 mL/min or less during two consecutive haemodialysis sessions, or the inability to initiate haemodialysis resulting from an inadequate blood flow.
- VII. Number of haemodialysis sessions during which dialysis could not be performed due to vascular access related problems, per person-year of haemodialysis treatment.
- VIII. The number of haemodialysis sessions with cannulation difficulties (i.e. needing >1 attempt to place and secure two dialysis needles) and cannulation failure (i.e. the inability to place and secure two dialysis needles) per person-year of haemodialysis treatment.

5.2 Analysis methods

5.2.1. Primary outcome

The number of access-related interventions required for each patient-year of haemodialysis treatment will be analysed using a general linear model with Poisson distribution and identity link, and with time as off-set variable. Both intervention groups (arteriovenous graft and central venous catheter placement) will be compared to the control group of autologous arteriovenous fistula creation. Vascular access-related intervention rates per patient-year will be summarized by treatment group and presented in a table. Between-group comparisons versus the control group (autologous AVF) will be expressed as incident rate ratios (IRR) with 97.5% confidence intervals (CI) and corresponding p-values. The IRR results can be visually presented in a forest plot, with the control group as reference (IRR = 1) and error bars representing the 97.5% CI. A p-value < 0.025 will be considered statistically significant. The sample size estimates for the trial have been adjusted for this double comparison. The models will be additionally adjusted for treatment centre by adding a random intercept or dummy variables to the model. Adjustment for participating centre via a random intercept or dummy variables will not be performed in case a substantial number of centres have fewer than five participants which would result in unstable model estimates, an increased risk of overfitting, and potential convergence issues. Every effort is made to establish eligibility of participants prior to randomization; no withdrawals due to ineligibility are allowed and the analyses include all participants enrolled. Non-adherence to the allocated treatment group is expected as patients cross over to another surgical strategy for vascular access. Non-adherence is minimized by recommending efforts to continue treatment as randomized when confronted with adverse events. The primary analysis will be on the intention to treat population (i.e. no participants are withdrawn from analysis for lack of adherence to treatment allocation); exploratory on-treatment analyses will be performed.

5.2.2. Secondary outcomes

Formal statistical comparisons will be made for the following outcomes (the number of formal comparisons is limited to reduce the chance of false-positive findings):

- SF-12 / DSI and SF-VAQ summary scores using generalized estimating equations (patient-reported outcome measures).
- The number of access-related serious adverse events per person-year using general linear models with Poisson distribution. Both intervention groups (AVG and CVC) will be compared to the control group of AVF creation. Vascular access-related serious adverse events per patient-year will be summarized by treatment group and presented in a table. Mortality using Cox regression (safety outcomes) will be reported using a table.

- The number of days admitted to hospital or visiting out-patient clinics for any reason per person-year (including haemodialysis sessions) using student t-tests. Both intervention groups (AVG and CVC) will be compared to the control group of AVF creation. The total number of days admitted to hospital or visiting out-patient clinics for any reason per person-year will be summarized by treatment group and presented in a table.

5.3. Missing data

Every effort is made to avoid missing data, which specifically includes assistance from dialysis nurses in obtaining patient-reported outcome measures during dialysis sessions. Primary outcome data are not expected to be missing, as interventions on vascular access will be reported in the patients' medical files. We expect no loss to follow-up in the study participants since they are observed three times per week in the dialysis unit. Patient-reported outcome measures will be analysed using generalized estimating equations that allow for missing data. Other missing data will be handled by using multiple imputation with regression methods, performing standard analyses for each imputation cycle considering the variability across the imputation cycles in the final analysis. The results of these analyses will be pooled using the Rubin's rule. Outliers will not be removed from the analysis unless the data can clearly be shown to be erroneous.

5.4 Additional analyses

Statistical analyses of outcomes not mentioned in the formal comparisons above are considered exploratory. A comparison of included and excluded patients is done to provide insight into the external validity of the clinical trial.

Exploratory analyses will be done with adjustment for Dusseux risk score and frailty scores including interaction terms with the treatment group. The primary outcome will also be analysed with major interventions having twice the weight of minor interventions and for different phases of the vascular access life cycle. Subgroup analyses will be done for patients who had already started haemodialysis treatment with a temporary central venous catheter at enrolment and for centres with aggressive versus conservative strategies with regards to vascular access surveillance and pre-emptive correction of access stenosis.

5.5 Interim analysis

Interim analysis has already been described in section 2.5.

5.6 Harms

Safety endpoints are vascular access related (serious) adverse events. Statistical analysis of these endpoints have been described in section 5.1.2.

5.7 Statistical software

Statistical analysis will be done with the latest available version of R (R-Project) or SPSS (IBM).

5.8 References

None

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Access-related days

Hospital admission days (all causes)

Hospital admission days (access-related)

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Total days

Access-related days

Hospital admission days (all causes)

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Access-related days

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Assisted Primary Patency

Secondary Patency

Primary Functional Patency

Assisted Primary Functional Patency

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Primary Patency

Assisted Primary Patency

Secondary Patency

Primary Functional Patency

Assisted Primary Functional Patency

Secondary Functional Patency

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Table 1A: Baseline characteristics – Demographics

Baseline characteristics	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	Central venous catheter (n= ##)
Age (years)	### (SD ###)	### (SD ###)	### (SD ###)
- Age <70 years	###% (n= ###)	###% (n= ###)	###% (n= ###)
Sex (male)	###% (n= ###)	###% (n= ###)	###% (n= ###)
Height (cm)	### (SD ###)	### (SD ###)	### (SD ###)
Weight (kg)	### (SD ###)	### (SD ###)	### (SD ###)
Body Mass Index (kg/m2)	### (SD ###)	### (SD ###)	### (SD ###)
Current smoker	###% (n= ###/###)	###% (n= ###/###)	###% (n= ###/###)
Primary renal disease			
- Diabetes mellitus	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Glomerulonephritis	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Hypertension	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Polycystic kidney disease	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Pyelonephritis	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Vascular nephropathy	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Other	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Unknown	###% (n= ###)	###% (n= ###)	###% (n= ###)
Previous kidney replacement therapy			
- No	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Yes, haemodialysis	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Yes, peritoneal dialysis	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Yes, kidney Transplantation	###% (n= ###)	###% (n= ###)	###% (n= ###)
Prevalent haemodialysis patient			
- Yes	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Duration of haemodialysis treatment (months)	### (SD ###)	### (SD ###)	### (SD ###)
Serum albumin (gr/L)	### (SD ###)	### (SD ###)	### (SD ###)

Baseline characteristics at inclusion, stratified by randomized type of vascular access. Continuous variables were tested for normal distribution using histograms and are presented as mean \pm SD. Categorical variables are presented as percentages.

Table 1B: Baseline characteristics – Comorbidities and antithrombotic therapy

Comorbidities	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	Central venous catheter (n= ##)
Arterial hypertension	####% (n= ###/###)	####% (n= ###/###)	####% (n= ###/###)
Diabetes mellitus	####% (n= ###/###)	####% (n= ###/###)	####% (n= ###/###)
Ischemic heart disease	####% (n= ###/###)	####% (n= ###/###)	####% (n= ###/###)
Cerebrovascular disease	####% (n= ###/###)	####% (n= ###/###)	####% (n= ###/###)
Congestive heart failure			
- No	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Yes, NYHA class I	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Yes, NYHA class II	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Yes, NYHA class III	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Yes, NYHA class IV	####% (n= ###)	####% (n= ###)	####% (n= ###)
Cardiac arrhythmia	####% (n= ###)	####% (n= ###)	####% (n= ###)
Pacemaker	####% (n= ###)	####% (n= ###)	####% (n= ###)
Peripheral vascular disease			
- No	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Yes, Fontaine I - II	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Yes, Fontaine III - IV	####% (n= ###)	####% (n= ###)	####% (n= ###)
Chronic lung disease	####% (n= ###)	####% (n= ###)	####% (n= ###)
Active malignancy	####% (n= ###)	####% (n= ###)	####% (n= ###)
Severe behavioral disorder	####% (n= ###)	####% (n= ###)	####% (n= ###)
Antithrombotic therapy			
- Antiplatelet therapy	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Dual antiplatelet therapy	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Direct Oral Anticoagulant	####% (n= ###)	####% (n= ###)	####% (n= ###)
- Vitamin K antagonist	####% (n= ###)	####% (n= ###)	####% (n= ###)

Baseline comorbidities and antithrombotic therapy at inclusion, stratified by randomized type of vascular access. Continuous variables were tested for normal distribution using histograms and are presented as mean \pm SD. Categorical variables are presented as percentages.

Table 1C: Baseline characteristics – Frailty scores

Frailty scores	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	Central venous catheter (n= ##)
Clinical Frailty Scale (mean)	### (SD ###)	### (SD ###)	### (SD ###)
- Very fit - managing well (1-3)	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Mild frailty - moderate frailty (4-6)	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Severe frailty - terminally ill (7-9)	###% (n= ###)	###% (n= ###)	###% (n= ###)
Nephro-geriatric assessment (DIALOGICA)			
Mobility			
- Walks independently, with a cane or walker if needed	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Walks with the assistance of another person	###% (n= ###)	###% (n= ###)	###% (n= ###)
- Bed- or wheelchair-bound	###% (n= ###)	###% (n= ###)	###% (n= ###)

Baseline frailty scores at inclusion, stratified by randomized type of vascular access. Continuous variables were tested for normal distribution using histograms and are presented as mean \pm SD. Categorical variables are presented as percentages.

Table 1D: Baseline characteristics – Duplex ultrasound results

Duplex ultrasound results	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	Central venous catheter (n= ##)
Right arm			
Systolic blood pressure (mmHg)	### (SD ###)	### (SD ###)	### (SD ###)
Diastolic blood pressure (mmHg)	### (SD ###)	### (SD ###)	### (SD ###)
Digital-brachial index	### (SD ###)	### (SD ###)	### (SD ###)
Brachial artery			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Radial artery			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Cephalic vein forearm			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Cephalic vein upper arm			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Basilic vein upper arm			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Jugular vein thrombosis	###% (n= ###)	###% (n= ###)	###% (n= ###)
Left arm			
Systolic blood pressure (mmHg)	### (SD ###)	### (SD ###)	### (SD ###)
Diastolic blood pressure (mmHg)	### (SD ###)	### (SD ###)	### (SD ###)
Digital-brachial index	### (SD ###)	### (SD ###)	### (SD ###)
Brachial artery			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Radial artery			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Cephalic vein forearm			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Cephalic vein upper arm			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Basilic vein upper arm			
- Mean diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
- Smallest diameter (mm)	### (SD ###)	### (SD ###)	### (SD ###)
Jugular vein thrombosis	### (SD ###)	### (SD ###)	### (SD ###)

Duplex ultrasound results before inclusion, stratified by randomized type of vascular access. Venous diameters were assessed with a tourniquet applied. Arterial diameters were measured at the luminal (inner) side of the vessel wall. If a vessel was measured at multiple levels, the mean and the smallest diameter are reported.

Continuous variables are presented as mean \pm SD. Categorical variables are presented as percentages. Missing values indicate that the vessel was not assessed.

Table 1E: Comparison of patients receiving haemodialysis with a temporary central venous catheter at inclusion and predialysis patients

	Prevalent haemodialysis with a temporary central venous catheter at inclusion (n= ##)	Predialysis at inclusion (n= ##)	p- value
Baseline characteristics			
Age (years)	### (SD ###)	### (SD ###)	###
Sex (male)	###% (n= ###)	###% (n= ###)	###
Height (cm)	### (SD ###)	### (SD ###)	###
Weight (kg)	### (SD ###)	### (SD ###)	###
Body Mass Index (kg/m2)	### (SD ###)	### (SD ###)	###
Current smoker	###% (n= ###/###)	###% (n= ###/###)	###
Primary renal disease			###
- Diabetes mellitus	###% (n= ###)	###% (n= ###)	
- Glomerulonephritis	###% (n= ###)	###% (n= ###)	
- Hypertension	###% (n= ###)	###% (n= ###)	
- Polycystic kidney disease	###% (n= ###)	###% (n= ###)	
- Pyelonephritis	###% (n= ###)	###% (n= ###)	
- Vascular nephropathy	###% (n= ###)	###% (n= ###)	
- Other	###% (n= ###)	###% (n= ###)	
- Unknown	###% (n= ###)	###% (n= ###)	
Previous kidney replacement therapy			###
- No	###% (n= ###)	###% (n= ###)	
- Yes, haemodialysis	###% (n= ###)	###% (n= ###)	
- Yes, peritoneal dialysis	###% (n= ###)	###% (n= ###)	
- Yes, kidney Transplantation	###% (n= ###)	###% (n= ###)	
- Duration of haemodialysis treatment (months)	### (SD ###)		
Serum albumin (gr/L)	### (SD ###)	### (SD ###)	###

Baseline characteristics stratified by haemodialysis status at inclusion (prevalent haemodialysis with a temporary central venous catheter vs. predialysis). Continuous variables are presented as mean \pm SD.

Categorical variables are presented as percentages.

The study groups were compared with student t-test for continuous variables (or with Mann-Whitney U-test when the data was not normally distributed) and with Chi-squared test for categorical variables (or with Fisher exact test when the expected cell count was less than 5).

	Prevalent haemodialysis with a temporary central venous catheter at inclusion (n= ##)	Predialysis at inclusion (n= ##)	p- value
Comorbidities			
Arterial hypertension	####% (n= ###/###)	####% (n= ###/###)	###
Diabetes mellitus	####% (n= ###/###)	####% (n= ###/###)	###
Ischemic heart disease	####% (n= ###/###)	####% (n= ###/###)	###
Cerebrovascular disease	####% (n= ###/###)	####% (n= ###/###)	###
Congestive heart failure			
- No	####% (n= ###)	####% (n= ###)	###
- Yes, NYHA class I	####% (n= ###)	####% (n= ###)	
- Yes, NYHA class II	####% (n= ###)	####% (n= ###)	
- Yes, NYHA class III	####% (n= ###)	####% (n= ###)	
- Yes, NYHA class IV	####% (n= ###)	####% (n= ###)	
Cardiac arrhythmia	####% (n= ###)	####% (n= ###)	###
Pacemaker	####% (n= ###)	####% (n= ###)	###
Peripheral vascular disease			
- No	####% (n= ###)	####% (n= ###)	###
- Yes, Fontaine I - II	####% (n= ###)	####% (n= ###)	
- Yes, Fontaine III - IV	####% (n= ###)	####% (n= ###)	
Chronic lung disease	####% (n= ###)	####% (n= ###)	###
Active malignancy	####% (n= ###)	####% (n= ###)	###
Severe behavioral disorder	####% (n= ###)	####% (n= ###)	###
Anticoagulant therapy			
- Antiplatelet therapy	####% (n= ###)	####% (n= ###)	###
- Dual antiplatelet therapy	####% (n= ###)	####% (n= ###)	
- Direct oral anticoagulant	####% (n= ###)	####% (n= ###)	
- Vitamin K antagonist	####% (n= ###)	####% (n= ###)	

Baseline comorbidities stratified by haemodialysis status at inclusion (prevalent haemodialysis with temporary central venous catheter vs. predialysis). Continuous variables are presented as mean \pm SD. Categorical variables are presented as percentages.

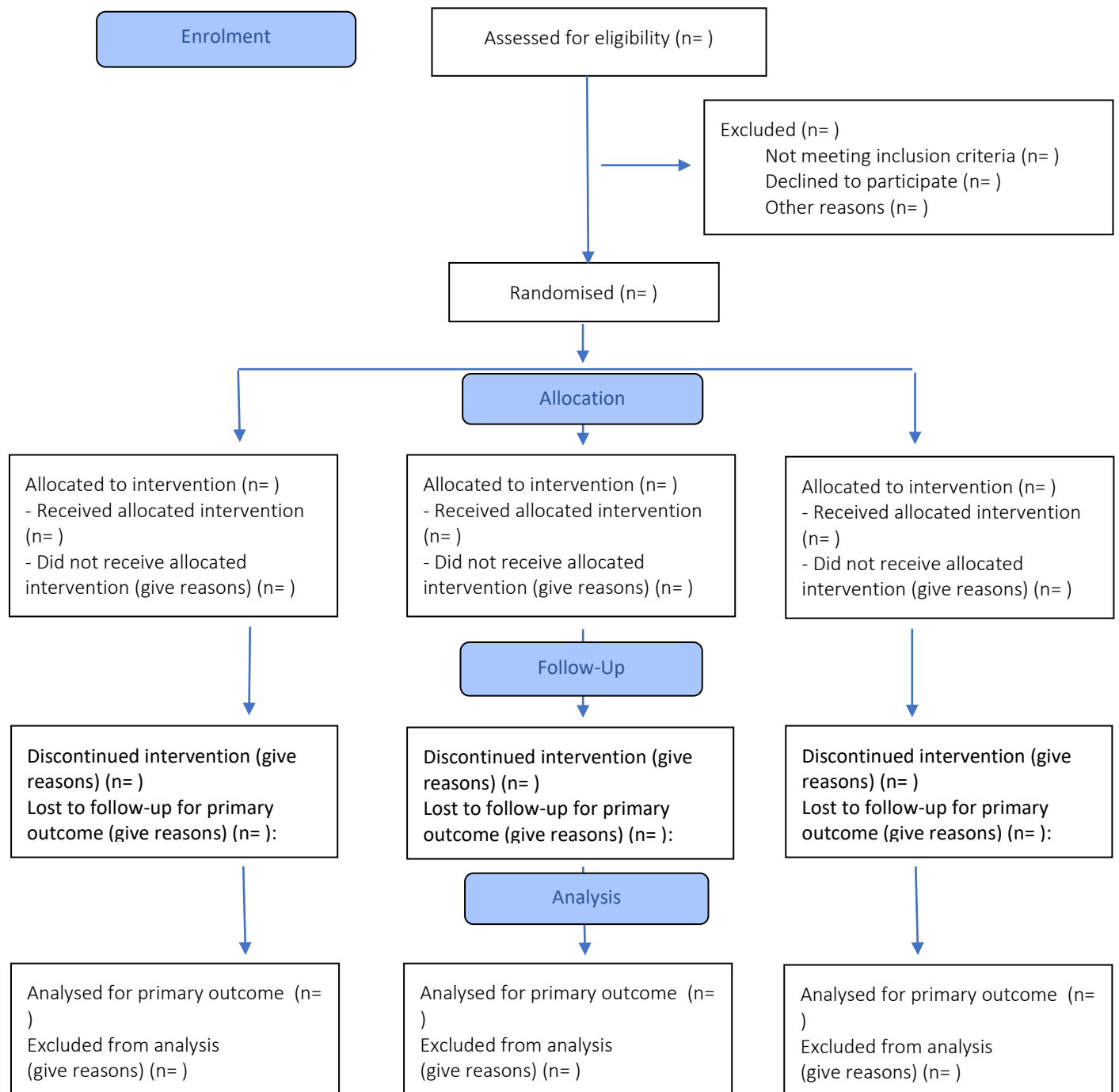
The study groups were compared with Chi-squared test for categorical variables (or with Fisher exact test when the expected cell count was less than 5).

	Prevalent haemodialysis with a temporary central venous catheter at inclusion (n= ##)	Predialysis at inclusion (n= ##)	p- value
Frailty scores			
Clinical Frailty Scale (mean)	### (SD ###)	### (SD ###)	###
- Very fit - managing well (1-3)	###% (n= ###)	###% (n= ###)	###
- Mild to moderate frailty (4-6)	###% (n= ###)	###% (n= ###)	
- Severe frailty - terminally ill (7-9)	###% (n= ###)	###% (n= ###)	
Nephro-geriatric assessment (DIALOGICA)			###
Mobility			###
- Walks independently, with a cane or walker if needed	###% (n= ###)	###% (n= ###)	
- Walks with the assistance of another person	###% (n= ###)	###% (n= ###)	
- Bed- or wheelchair-bound	###% (n= ###)	###% (n= ###)	

Baseline characteristics stratified by haemodialysis status at inclusion (prevalent haemodialysis with a temporary central venous catheter vs. predialysis). Continuous variables are presented as mean \pm SD. Categorical variables are presented as percentages.

The study groups were compared with student t-test for continuous variables (or with Mann-Whitney U-test when the data was not normally distributed) and with Chi-squared test for categorical variables (or with Fisher exact test when the expected cell count was less than 5).

Figure 2A: CONSORT 2025 flow diagram of screening, randomization, and follow-up



Flow diagram of the progress through the phases of a randomised trial of three groups (that is, enrolment, intervention allocation, follow-up, and data analysis).(5)

Table 2B: Comparison of enrolled patients with unselected population – Baseline characteristics

Baseline characteristics	Enrolled patients (n= ##)	Unselected population (n= ##)	p-value
Age (years)	### (SD ###)	### (SD ###)	###
Sex (male)	###% (n= ###)	###% (n= ###)	###
Height (cm)	### (SD ###)	### (SD ###)	###
Weight (kg)	### (SD ###)	### (SD ###)	###
Body Mass Index (kg/m2)	### (SD ###)	### (SD ###)	###
Primary renal disease			###
- Diabetes mellitus	###% (n= ###)	###% (n= ###)	
- Glomerulonephritis	###% (n= ###)	###% (n= ###)	
- Hypertension	###% (n= ###)	###% (n= ###)	
- Polycystic kidney disease	###% (n= ###)	###% (n= ###)	
- Pyelonephritis	###% (n= ###)	###% (n= ###)	
- Vascular nephropathy	###% (n= ###)	###% (n= ###)	
- Other	###% (n= ###)	###% (n= ###)	
- Unknown	###% (n= ###)	###% (n= ###)	
Previous kidney replacement therapy			###
- No	###% (n= ###)	###% (n= ###)	
- Yes, haemodialysis	###% (n= ###)	###% (n= ###)	
- Yes, peritoneal dialysis	###% (n= ###)	###% (n= ###)	
- Yes, kidney Transplantation	###% (n= ###)	###% (n= ###)	
Prevalent haemodialysis patient			
- Yes	###% (n= ###)	###% (n= ###)	###
- Duration of haemodialysis treatment (months)	### (SD ###)	### (SD ###)	###
Serum albumin (gr/L)	### (SD ###)	### (SD ###)	###

Baseline characteristics for enrolled patients and the unselected patients at the time of screening or inclusion (for enrolled patients). Continuous variables are presented as mean \pm SD. Categorical variables are presented as percentages.

The study groups were compared with student t-test for continuous variables (or with Mann-Whitney U-test when the data was not normally distributed) and with Chi-squared test for categorical variables (or with Fisher exact test when the expected cell count was less than 5).

Table 2C: Comparison of enrolled patients with unselected haemodialysis population - Vascular-access related interventions per person year of haemodialysis

Vascular access related interventions per person year of haemodialysis	Enrolled patients (... person-years)		Unselected population (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)	
All vascular-access related interventions (...-...) (...-...)	###
Surgical interventions (...-...) (...-...)	###
- Creation of an AVF (...-...) (...-...)	###
- Creation of an AVG (...-...) (...-...)	###
- Patch angioplasty or anastomotic revision for stenosis (...-...) (...-...)	###
- Open thrombectomy (...-...) (...-...)	###
- Ligation and/or excision of an AVF (...-...) (...-...)	###
- Ligation and/or excision of an AVG (...-...) (...-...)	###
- Repair of a (pseudo)aneurysm (...-...) (...-...)	###
- Surgical ligation of a collateral vein (...-...) (...-...)	###
- Vein superficialization or transposition (...-...) (...-...)	###
- Distal revascularization with interval ligation (...-...) (...-...)	###
- Proximalization of the arteriovenous anastomosis (...-...) (...-...)	###
- Revision using distal inflow (...-...) (...-...)	###
- Vascular access banding (...-...) (...-...)	###
Endovascular interventions (...-...) (...-...)	###
- Angiography with PTA and/or stent placement (...-...) (...-...)	###
- Percutaneous thrombectomy and/or thrombolysis (...-...) (...-...)	###
- Endovascular embolization of a collateral vein (...-...) (...-...)	###
Central venous catheter interventions (...-...) (...-...)	###
- Insertion of a CVC (...-...) (...-...)	###
- Exchange of a CVC over a guidewire (...-...) (...-...)	###
- Removal of CVC (...-...) (...-...)	###

Vascular access related interventions per person year of haemodialysis for enrolled patients and the unselected patients. The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. Study groups were compared using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty.

Figure 2D: Comparison of enrolled patients with unselected haemodialysis population – Survival

Kaplan-Meier curves depict time-to-event survival for the enrolled patients and unselected haemodialysis patients. Survival time was defined as the time from randomization (for enrolled patients) or screening (for unselected patients) to death from any cause. Patients who remained alive at the end of the study were censored at their last known follow-up date.

Study groups were compared using log-rank tests.

Table 2E: Patient flow and key outcomes per study site

Study site	Screened for eligibility	Included*	Patient allocation AVF / AVG / CVC	Treatment non-adherence**	Crossover**	Total follow-up time (years)	Vascular access related interventions	Mortality**
Albert Schweitzer hospital	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Amphia	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Canisius Wilhelmina hospital	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Catharina hospital	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Elisabeth-TweeSteden hospital	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Franciscus	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Haaglanden Medical Center	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Isala	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Leids University Medical Center	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Maastricht University Medical Center+	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Máxima Medical Center	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Medisch Spectrum Twente	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Noordwest Ziekenhuisgroep	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
OLVG	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Rijnstate	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Spaarne Gasthuis	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
VieCuri	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Ziekenhuisgroep Twente	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)
Zuyderland	###	### (%)	### / ### / ###	### (##%)	### (##%)	###	###	### (##%)

Patient flow and key outcomes per study site. * Included patients are presented as absolute number, followed by the percentage of patients screened for eligibility. ** Variables are presented as absolute numbers, followed by the percentage of included patients.

Table 2F: Treatment non-adherence and crossovers

Treatment non-adherence and crossovers	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Treatment non-adherence	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
- Switch to AVF		###% (n= ###)		###% (n= ###)	
- Switch to AVG	###% (n= ###)			###% (n= ###)	
- Switch to CVC	###% (n= ###)	###% (n= ###)			
Crossovers	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
- Crossover to AVF		###% (n= ###)		###% (n= ###)	
- Crossover to AVG	###% (n= ###)			###% (n= ###)	
- Crossover to CVC	###% (n= ###)	###% (n= ###)			

Treatment non-adherence and crossovers, stratified by the randomized type of vascular access. Patients were considered non-adherent if they received a vascular access type different from the allocated type after having received the allocated access. Patients were considered crossovers if they received a vascular access type different from the allocated type without ever receiving the allocated access.

The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using Chi-squared tests for categorical variables (or with Fisher exact test when the expected cell count was less than 5). Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 2G: End of study outcomes per study group

End of study outcomes	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Allocated vascular access created	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
Initiated haemodialysis treatment	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
Died	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
Stopped haemodialysis treatment	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
- Recovery of kidney function	###% (n= ###)	###% (n= ###)		###% (n= ###)	
- Kidney transplantation	###% (n= ###)	###% (n= ###)		###% (n= ###)	
- Switch to peritoneal dialysis	###% (n= ###)	###% (n= ###)		###% (n= ###)	
- Other reason	###% (n= ###)	###% (n= ###)		###% (n= ###)	
Withdrawals	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
Lost to follow-up	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###
Completed study	###% (n= ###)	###% (n= ###)	###	###% (n= ###)	###

End-of-study outcomes for all randomized patients, summarized per study group. Values represent the status of patients at study completion, including treatment outcomes and survival. Percentages are given relative to the total number of patients randomized in each group, followed by the absolute number.

The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using Chi-squared tests for categorical variables (or with Fisher exact test when the expected cell count was less than 5).

Table 3A: Vascular access-related interventions per person year of haemodialysis (primary analysis, intention-to-treat)

Vascular access related interventions per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97,5% CI)	N	Event rate (97,5% CI)		N	Event rate (97,5% CI)	
All vascular-access related interventions (...-...) (...-...)	### (...-...)	###
Surgical interventions (...-...) (...-...)	### (...-...)	###
- Creation of an AVF (...-...) (...-...)	### (...-...)	###
- Creation of an AVG (...-...) (...-...)	### (...-...)	###
- Patch angioplasty or anastomotic revision for stenosis (...-...) (...-...)	### (...-...)	###
- Open thrombectomy (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVF (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVG (...-...) (...-...)	### (...-...)	###
- Repair of a (pseudo)aneurysm (...-...) (...-...)	### (...-...)	###
- Surgical ligation of a collateral vein (...-...) (...-...)	### (...-...)	###
- Vein superficialization or transposition (...-...) (...-...)	### (...-...)	###
- Distal revascularization with interval ligation (...-...) (...-...)	### (...-...)	###
- Proximalization of the arteriovenous anastomosis (...-...) (...-...)	### (...-...)	###
- Revision using distal inflow (...-...) (...-...)	### (...-...)	###
- Vascular access banding (...-...) (...-...)	### (...-...)	###
Endovascular interventions (...-...) (...-...)	### (...-...)	###
- Angiography with PTA and/or stent placement (...-...) (...-...)	### (...-...)	###
- Percutaneous thrombectomy and/or thrombolysis (...-...) (...-...)	### (...-...)	###
- Endovascular embolization of a collateral vein (...-...) (...-...)	### (...-...)	###
Central venous catheter interventions (...-...) (...-...)	### (...-...)	###
- Insertion of a CVC (...-...) (...-...)	### (...-...)	###
- Exchange of a CVC over a guidewire (...-...) (...-...)	### (...-...)	###
- Removal of CVC (...-...) (...-...)	### (...-...)	###

Intention-to-treat analysis for vascular access related interventions per person year of haemodialysis, according to randomized type of vascular access. The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty

Table 3B: Vascular access-related interventions per person year of haemodialysis (per protocol analysis)

Vascular access related interventions per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97,5% CI)	N	Event rate (97,5% CI)		N	Event rate (97,5% CI)	
All vascular-access related interventions (...-...) (...-...)	### (...-...)	###
Surgical interventions (...-...) (...-...)	### (...-...)	###
- Creation of an AVF (...-...) (...-...)	### (...-...)	###
- Creation of an AVG (...-...) (...-...)	### (...-...)	###
- Patch angioplasty or anastomotic revision for stenosis (...-...) (...-...)	### (...-...)	###
- Open thrombectomy (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVF (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVG (...-...) (...-...)	### (...-...)	###
- Repair of a (pseudo)aneurysm (...-...) (...-...)	### (...-...)	###
- Surgical ligation of a collateral vein (...-...) (...-...)	### (...-...)	###
- Vein superficialization or transposition (...-...) (...-...)	### (...-...)	###
- Distal revascularization with interval ligation (...-...) (...-...)	### (...-...)	###
- Proximalization of the arteriovenous anastomosis (...-...) (...-...)	### (...-...)	###
- Revision using distal inflow (...-...) (...-...)	### (...-...)	###
- Vascular access banding (...-...) (...-...)	### (...-...)	###
Endovascular interventions (...-...) (...-...)	### (...-...)	###
- Angiography with PTA and/or stent placement (...-...) (...-...)	### (...-...)	###
- Percutaneous thrombectomy and/or thrombolysis (...-...) (...-...)	### (...-...)	###
- Endovascular embolization of a collateral vein (...-...) (...-...)	### (...-...)	###
Central venous catheter interventions (...-...) (...-...)	### (...-...)	###
- Insertion of a CVC (...-...) (...-...)	### (...-...)	###
- Exchange of a CVC over a guidewire (...-...) (...-...)	### (...-...)	###
- Removal of CVC (...-...) (...-...)	### (...-...)	###

Per protocol analysis for vascular access related interventions per person year of haemodialysis, according to randomized type of vascular access, excluding patients with treatment crossover or non-adherence. The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable. Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty

Table 3C: Vascular access-related interventions per person year of study follow-up (intention-to-treat analysis)

Vascular access related interventions per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97,5% CI)	N	Event rate (97,5% CI)		N	Event rate (97,5% CI)	
All vascular-access related interventions (...-...) (...-...)	### (...-...)	###
Surgical interventions (...-...) (...-...)	### (...-...)	###
- Creation of an AVF (...-...) (...-...)	### (...-...)	###
- Creation of an AVG (...-...) (...-...)	### (...-...)	###
- Patch angioplasty or anastomotic revision for stenosis (...-...) (...-...)	### (...-...)	###
- Open thrombectomy (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVF (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVG (...-...) (...-...)	### (...-...)	###
- Repair of a (pseudo)aneurysm (...-...) (...-...)	### (...-...)	###
- Surgical ligation of a collateral vein (...-...) (...-...)	### (...-...)	###
- Vein superficialization or transposition (...-...) (...-...)	### (...-...)	###
- Distal revascularization with interval ligation (...-...) (...-...)	### (...-...)	###
- Proximalization of the arteriovenous anastomosis (...-...) (...-...)	### (...-...)	###
- Revision using distal inflow (...-...) (...-...)	### (...-...)	###
- Vascular access banding (...-...) (...-...)	### (...-...)	###
Endovascular interventions (...-...) (...-...)	### (...-...)	###
- Angiography with PTA and/or stent placement (...-...) (...-...)	### (...-...)	###
- Percutaneous thrombectomy and/or thrombolysis (...-...) (...-...)	### (...-...)	###
- Endovascular embolization of a collateral vein (...-...) (...-...)	### (...-...)	###
Central venous catheter interventions (...-...) (...-...)	### (...-...)	###
- Insertion of a CVC (...-...) (...-...)	### (...-...)	###
- Exchange of a CVC over a guidewire (...-...) (...-...)	### (...-...)	###
- Removal of CVC (...-...) (...-...)	### (...-...)	###

Intention-to-treat analysis for vascular access related interventions per person year, according to randomized type of vascular access. The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty

Table 3D: Vascular access-related interventions per person year of study follow-up (per protocol analysis)

Vascular access related interventions per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97,5% CI)	N	Event rate (97,5% CI)		N	Event rate (97,5% CI)	
All vascular-access related interventions (...-...) (...-...)	### (...-...)	###
Surgical interventions (...-...) (...-...)	### (...-...)	###
- Creation of an AVF (...-...) (...-...)	### (...-...)	###
- Creation of an AVG (...-...) (...-...)	### (...-...)	###
- Patch angioplasty or anastomotic revision for stenosis (...-...) (...-...)	### (...-...)	###
- Open thrombectomy (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVF (...-...) (...-...)	### (...-...)	###
- Ligation and/or excision of an AVG (...-...) (...-...)	### (...-...)	###
- Repair of a (pseudo)aneurysm (...-...) (...-...)	### (...-...)	###
- Surgical ligation of a collateral vein (...-...) (...-...)	### (...-...)	###
- Vein superficialization or transposition (...-...) (...-...)	### (...-...)	###
- Distal revascularization with interval ligation (...-...) (...-...)	### (...-...)	###
- Proximalization of the arteriovenous anastomosis (...-...) (...-...)	### (...-...)	###
- Revision using distal inflow (...-...) (...-...)	### (...-...)	###
- Vascular access banding (...-...) (...-...)	### (...-...)	###
Endovascular interventions (...-...) (...-...)	### (...-...)	###
- Angiography with PTA and/or stent placement (...-...) (...-...)	### (...-...)	###
- Percutaneous thrombectomy and/or thrombolysis (...-...) (...-...)	### (...-...)	###
- Endovascular embolization of a collateral vein (...-...) (...-...)	### (...-...)	###
Central venous catheter interventions (...-...) (...-...)	### (...-...)	###
- Insertion of a CVC (...-...) (...-...)	### (...-...)	###
- Exchange of a CVC over a guidewire (...-...) (...-...)	### (...-...)	###
- Removal of CVC (...-...) (...-...)	### (...-...)	###

Per protocol analysis for vascular access related interventions per person year, according to randomized type of vascular access excluding patients with treatment crossover or non-adherence. The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty

Table 3E: Vascular access-related interventions stratified by intervention type and phase of the vascular access life cycle per person year of haemodialysis treatment

Vascular access related interventions per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
All vascular-access related interventions (...-...) (...-...)	 (...-...)	
Intervention type								
- Major (...-...) (...-...)	### (...-...)	###
- Minor (...-...) (...-...)	### (...-...)	###
Weighted vascular-access related interventions (...-...) (...-...)	### (...-...)	###
Vascular access life cycle								
- Maturation (...-...) (...-...)	### (...-...)	###
- Functional (...-...) (...-...)	### (...-...)	###
- Next access (...-...) (...-...)	### (...-...)	###

Intention-to-treat analysis for vascular access related interventions per person year, according to randomized type of vascular access. Major interventions are interventions using general anaesthesia or requiring hospital admission for more than one day; other interventions are classified as minor interventions. The weighted analysis as done by counting major interventions twice and minor interventions once. The phases of the vascular access life cycle are: maturation (vascular access creation until functional), functional (functional until vascular access abandonment), next access (after abandonment of previous access). The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty

Table 3F: Subgroup analyses of the primary endpoint

Vascular access related interventions per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
All vascular-access related interventions (...-...) (...-...)	 (...-...)	
Dialysis status at randomization					###			###
- Predialysis (...-...) (...-...)	 (...-...)	
- On dialysis with CVC (...-...) (...-...)	 (...-...)	
Surveillance strategy					###			###
- Aggressive (...-...) (...-...)	 (...-...)	
- Conservative (...-...) (...-...)	 (...-...)	
Age (years)					###			###
Dusseux score					###			###
Clinical frailty score					###			###

Intention-to-treat analysis for vascular access related interventions per person year of haemodialysis treatment, according to randomized type of vascular access. Subgroup analyses were prespecified and are considered exploratory. Aggressive surveillance centres were defined as study sites applying a stricter vascular access surveillance strategy than recommended by the European Society for Vascular Surgery (ESVS) guidelines, whereas conservative surveillance centres applied a strategy equal to or less stringent than the ESVS recommendations.

The data are presented as number of interventions for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable and the subgroup variables of interest as single covariates (with age, Dusseux score, and Clinical frailty score analysed as continuous variables). P-values are for interaction terms of vascular access type x covariates. Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter. PTA: percutaneous transluminal angioplasty

Table 3G: Time between enrollment or vascular access creation and event

	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p- value	Central venous catheter (n= ###)	p- value
Time between enrollment and first vascular access creation (months)	### (IQR ###)	### (IQR ###)	###	### (IQR ###)	###
Time between enrollment and first haemodialysis treatment (months)	### (IQR ###)	### (IQR ###)	###	### (IQR ###)	###
Time between enrollment and functional vascular access (months)	### (IQR ###)	### (IQR ###)	###	### (IQR ###)	###
Time between vascular access creation and first haemodialysis treatment (months)	### (IQR ###)	### (IQR ###)	###	### (IQR ###)	###
Time between vascular access creation and functional vascular access (months)	### (IQR ###)	### (IQR ###)	###	### (IQR ###)	###

Data are presented as median \pm interquartile range (IQR). The study groups are compared with Mann-Whitney U-tests.

Figure 3H: Forest plot of subgroup analyses for the primary endpoint

Intention-to-treat analysis for vascular access related interventions per person year of haemodialysis treatment, according to randomized type of vascular access. In the forest plot, incident rate ratios (IRRs) with 97,5% confidence intervals of prespecified subgroups (predialysis vs on dialysis at enrolment, and aggressive vs conservative surveillance strategy) are presented for comparisons between arteriovenous grafts and arteriovenous fistulas and between central venous catheters and arteriovenous fistulas. Statistical analysis was described in Table 3F.

Figure 3I: Forest plot of subgroup analyses for the primary endpoint with major interventions weighted double using incident rate ratios (IRR)

Intention-to-treat analysis for vascular access related interventions per person year of haemodialysis treatment, with major interventions weighted double. In the forest plot, incident rate ratios (IRRs) with 97,5% confidence intervals are presented for comparisons between arteriovenous grafts and arteriovenous fistulas and between central venous catheters and arteriovenous fistulas.

Table 4A: Serious adverse events per person year (intention-to-treat analysis)

Serious adverse events per person year	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
All serious adverse events								
- Resulting in death (...-...) (...-...)	### (...-...)	###
- Life threatening (...-...) (...-...)	### (...-...)	###
- Requiring in hospitalisation or prolongation of hospitalisation (...-...) (...-...)	### (...-...)	###
- Resulting in significant disability or incapacity (...-...) (...-...)	### (...-...)	###
- Other (...-...) (...-...)	### (...-...)	###
Vascular access-related serious adverse events								
- Resulting in death (...-...) (...-...)	### (...-...)	###
- Life threatening (...-...) (...-...)	### (...-...)	###
- Requiring hospitalisation or prolongation of hospitalisation (...-...) (...-...)	### (...-...)	###
- Resulting in significant disability or incapacity (...-...) (...-...)	### (...-...)	###
- Other (...-...) (...-...)	### (...-...)	###

Intention-to-treat analysis for serious adverse events (SAEs) per person year, according to randomized type of vascular access. The data are presented as number of SAEs per person year for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 4B: Emergency room visits per person year (intention-to-treat analysis)

	AVF (... person-years)		AVG (... person-years)		p- value	CVC (... person-years)		p- value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Emergency room visits (...-...) (...-...)	### (...-...)	###

Intention to treat analysis of emergency room (ER) visits per person year, according to randomized type of vascular access. The data are presented as number of ER visits per person year for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 4C: Mortality by study group (intention-to-treat, Cox Regression Analysis)

	Hazard ratio (97,5% CI)	p-value
Vascular access type		###
- Arteriovenous fistulas	Reference	
- Arteriovenous grafts	... (...-...)	
Vascular access type		###
- Arteriovenous fistulas	Reference	
- Central venous catheters	... (...-...)	

Intention to treat analysis of mortality, according to randomized type of vascular access. Hazard ratios (HR) and corresponding 97,5% confidence intervals (CI) were estimated using univariable Cox proportional hazards regression, with the arteriovenous fistula (AVF) group as the reference. The proportional hazards assumption was assessed using Schoenfeld residuals and visual inspection of residual plots. In case of violation of the proportional hazards assumption, time-dependent Cox-regression will be used. The arteriovenous graft (AVG) and central venous catheter (CVC) groups were each compared with the AVF group in separate analyses.

Figure 4D: Kaplan–Meier curve for Overall Survival by study group (intention-to-treat analysis)

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan-Meier curves depict time-to-event survival for the study groups (intention-to-treat analysis) and include a table with patients at risk at various time points. Survival time was defined as the time from randomization to death from any cause. Patients who remained alive at the end of follow-up were censored at that time. Arteriovenous grafts were compared with arteriovenous fistulas and central venous catheters were compared with arteriovenous fistulas using log-rank tests.

Table 4E: Serious adverse events per person year (per protocol analysis)

Serious adverse events per person year	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
All serious adverse events								
- Resulting in death (...-...) (...-...)	### (...-...)	###
- Life threatening (...-...) (...-...)	### (...-...)	###
- Requiring in hospitalisation or prolongation of hospitalisation (...-...) (...-...)	### (...-...)	###
- Resulting in significant disability or incapacity (...-...) (...-...)	### (...-...)	###
- Other (...-...) (...-...)	### (...-...)	###
Vascular access-related serious adverse events								
- Resulting in death (...-...) (...-...)	### (...-...)	###
- Life threatening (...-...) (...-...)	### (...-...)	###
- Requiring hospitalisation or prolongation of hospitalisation (...-...) (...-...)	### (...-...)	###
- Resulting in significant disability or incapacity (...-...) (...-...)	### (...-...)	###
- Other (...-...) (...-...)	### (...-...)	###

Per protocol analysis for serious adverse events (SAEs) per person year, according to type of vascular access. The data are presented as number of SAEs per person year for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable. Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 4F: Emergency room visits per person year (per protocol analysis)

	AVF (... person-years)		AVG (... person-years)		p- value	CVC (... person-years)		p- value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Emergency room visits (...-...) (...-...)	### (...-...)	###

Per protocol analysis of emergency room (ER) visits per person year, according to randomized type of vascular access excluding patients with treatment crossover or non-adherence. The data are presented as number of ER visits per person year for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 4G: Mortality by type of vascular access (per protocol, Cox Regression Analysis)

	Hazard ratio (97.5% CI)	p-value
Vascular access type		###
- Arteriovenous fistulas	Reference	
- Arteriovenous grafts	... (...-...)	
Vascular access type		###
- Arteriovenous fistulas	Reference	
- Central venous catheters	... (...-...)	

Per protocol analysis of mortality, according to randomized type of vascular access excluding patients with treatment crossover or non-adherence. Hazard ratios (HR) and corresponding 97,5% confidence intervals (CI) were estimated using univariable Cox proportional hazards regression, with the arteriovenous fistula (AVF) group as the reference. The proportional hazards assumption was assessed using Schoenfeld residuals and visual inspection of residual plots. In case of violation of the proportional hazards assumption, time-dependent Cox-regression will be used. The arteriovenous graft (AVG) and central venous catheter (CVC) groups were each compared with the AVF group in separate analyses.

Figure 4H: Kaplan–Meier curve for Overall Survival by study group (per protocol analysis)

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan-Meier curves depict time-to-event survival for the study groups (per protocol analysis excluding patients with treatment crossover or non-adherence) and include a table with patients at risk at various time points. Survival time was defined as the time from randomization to death from any cause. Patients who remained alive at the end of follow-up were censored at that time. Arteriovenous grafts were compared with arteriovenous fistulas and central venous catheters were compared with arteriovenous fistulas using log-rank tests.

Table 5A: Vascular access-related adverse events per person-year (intention to treat analysis)

Vascular access-related complications	AVF (... person-years)		AVG (... person-years)		p- value	CVC (... person-years)		p- value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Pain (...-...) (...-...)	### (...-...)	###
- Not requiring daily analgesics (...-...) (...-...)	 (...-...)	
- Requiring daily analgesics (...-...) (...-...)	 (...-...)	
Central venous catheter infection (...-...) (...-...)	### (...-...)	###
- Sepsis / Bloodstream infection (...-...) (...-...)	### (...-...)	###
- Exit-site infection (...-...) (...-...)	 (...-...)	
- Tunnel infection (...-...) (...-...)	 (...-...)	
Arteriovenous fistula or graft infection (...-...) (...-...)	### (...-...)	###
Central venous catheter thrombolysis (...-...) (...-...)	### (...-...)	###
Vascular access related blood transfusion (...-...) (...-...)	### (...-...)	###
Hand ischemia (...-...) (...-...)	### (...-...)	###
- Grade 1 (...-...) (...-...)	 (...-...)	
- Grade 2 (...-...) (...-...)	 (...-...)	
- Grade 3 (...-...) (...-...)	 (...-...)	
- Grade 4 (...-...) (...-...)	 (...-...)	

Intention to treat analysis of vascular access–related adverse events according to randomized type of vascular access. The data are presented as number of vascular access-related adverse events per person year for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Pain was categorized according to the requirement for daily analgesic use. Catheter-related infections were classified as sepsis or catheter-related bloodstream infection, exit-site infection, or tunnel infection. Central venous catheter thrombolysis refers to the use of thrombolytic agents for catheter dysfunction. Vascular access–related blood transfusion includes transfusions attributed to access-related complications. Hand ischemia was graded according to severity as follows: Grade 1: Pale or cyanotic and/or cold hand, without pain. Grade 2: Pain during exertion or haemodialysis. Grade 3: Ischemic pain at rest. Grade 4: Ulcers, necrosis, and/or gangrene.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 5B: Vascular access-related adverse events per person-year (per protocol analysis)

Vascular access-related complications	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Pain (...-...) (...-...)	### (...-...)	###
- Not requiring daily analgesics (...-...) (...-...)	### (...-...)	###
- Requiring daily analgesics (...-...) (...-...)	### (...-...)	###
Central venous catheter infection (...-...) (...-...)	### (...-...)	###
- Sepsis / Bloodstream infection (...-...) (...-...)	### (...-...)	###
- Exit-site infection (...-...) (...-...)	### (...-...)	###
- Tunnel infection (...-...) (...-...)	### (...-...)	###
Arteriovenous fistula or graft infection (...-...) (...-...)	### (...-...)	###
Central venous catheter thrombolysis (...-...) (...-...)	### (...-...)	###
Vascular access related blood transfusion (...-...) (...-...)	### (...-...)	###
Hand ischemia (...-...) (...-...)	### (...-...)	###
- Grade 1 (...-...) (...-...)	### (...-...)	###
- Grade 2 (...-...) (...-...)	### (...-...)	###
- Grade 3 (...-...) (...-...)	### (...-...)	###
- Grade 4 (...-...) (...-...)	### (...-...)	###

Per protocol analysis of vascular access-related adverse events according to randomized type of vascular access excluding patients with treatment crossover or non-adherence. The data are presented as number of vascular access-related adverse events per person year for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable. Pain was categorized according to the requirement for daily analgesic use. Catheter-related infections were classified as sepsis or catheter-related bloodstream infection, exit-site infection, or tunnel infection. Central venous catheter thrombolysis refers to the use of thrombolytic agents for catheter dysfunction. Vascular access-related blood transfusion includes transfusions attributed to access-related complications. Hand ischemia was graded according to severity as follows: Grade 1: Pale or cyanotic and/or cold hand, without pain. Grade 2: Pain during exertion or haemodialysis. Grade 3: Ischemic pain at rest. Grade 4: Ulcers, necrosis, and/or gangrene.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 6A: Days admitted to hospital or visiting outpatient clinics per person-year

Days admitted to hospital or visiting outpatient clinics per person year	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Days visiting hospital (including dialysis) (...-...) (...-...)	### (...-...)	###
Days visiting hospital (access-related) (...-...) (...-...)	### (...-...)	###
Hospital admission days (all causes) (...-...) (...-...)	### (...-...)	###
Hospital admission days (access-related) (...-...) (...-...)	### (...-...)	###

Intention to treat analysis of the number of days admitted to the hospital or visiting outpatient clinics per person year, according to randomized type of vascular access. The data are presented as number of days for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 6B: Days admitted to hospital or visiting outpatient clinics per person-year, predialysis

Days admitted to hospital or visiting outpatient clinics per person year, predialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Days visiting hospital (including dialysis) (...-...) (...-...)	### (...-...)	###
Days visiting hospital (access-related) (...-...) (...-...)	### (...-...)	###
Hospital admission days (all causes) (...-...) (...-...)	### (...-...)	###
Hospital admission days (access-related) (...-...) (...-...)	### (...-...)	###

Analysis of the number of days admitted to the hospital or visiting outpatient clinics per person year in the predialysis phase, according to randomized type of vascular access. The data are presented as number of days for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 6C: Days admitted to hospital or visiting outpatient clinics per person-year, during dialysis treatment

Days admitted to hospital or visiting outpatient clinics per person year, on dialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Days visiting hospital (including dialysis) (...-...) (...-...)	### (...-...)	###
Days visiting hospital (access-related) (...-...) (...-...)	### (...-...)	###
Hospital admission days (all causes) (...-...) (...-...)	### (...-...)	###
Hospital admission days (access-related) (...-...) (...-...)	### (...-...)	###

Analysis of the number of days admitted to the hospital or visiting outpatient clinics per person year in the dialysis phase, according to randomized type of vascular access. The data are presented as number of days for the whole study group and as event rates with their 97,5% confidence interval based on Poisson distribution for the accumulated follow-up time in the whole study group. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 7A: Short form health survey (SF-12) scores over time by study group

Short form health survey (SF-12) scores (0-100)	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Predialysis			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	

Short form health survey (SF-12) scores over time by study group. SF-12 item scores were linearly transformed to a 0–100 scale, with 0 indicating the worst and 100 the best possible health status. Transformed score = $((\text{observed score} - \text{lowest possible score}) / (\text{score range})) \times 100$. Results are presented as mean \pm SD. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized linear mixed models stratified by dialysis status.

Table 7B: Box plots of short form health survey (SF-12) scores over time by study group

Distribution of SF-12 scores over time by study group. Box plots show SF-12 scores at each scheduled measurement occasion, stratified by study group: arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheter (CVC). Scores were transformed to a 0–100 scale, with higher scores indicating better health status. The horizontal line within each box represents the median, the boxes represent the interquartile range, whiskers extend to values within 1.5 times the interquartile range, and individual points indicate outliers. Numbers below the x-axis indicate the number of patients with available SF-12 scores at each time point.

Table 7C: Dialysis symptom index (DSI) scores over time by study group

Dialysis symptom index (DSI) scores (0-120) and number of symptoms (0-30)	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Predialysis - DSI scores			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - DSI scores			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - Number of symptoms			###		###
- Baseline	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 3 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 6 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 9 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 12 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
Dialysis - Number of symptoms			###		###
- Baseline	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 3 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 6 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 9 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	
- 12 months	### (IQR ###)	### (IQR ###)		### (IQR ###)	

Dialysis symptom index (DSI) scores and number of symptoms over time by study group. Total DSI scores were calculated by summing severity scores across all 30 items, the severity is rated on a 5-point Likert scale (usually 0="not at all" to 4="very much", range 0-120). In addition, the number of symptoms per patient was determined (range 0-30 symptoms). Results are presented as mean (standard deviation) or as median (interquartile range). The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized linear mixed models stratified by dialysis status.

Table 7D: Box plots of dialysis symptom index (DSI) scores over time by study group

Distribution of Dialysis Symptom Index scores over time by study group. Box plots show Dialysis Symptom Index (DSI) scores at each scheduled measurement occasion, stratified by study group: arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheter (CVC). The DSI total symptom severity score is calculated by summing severity scores across all 30 items and ranges from 0 to 120, with higher scores indicating greater symptom burden. The number of symptoms per patient ranges from 0 to 30. The horizontal line within each box represents the median, the boxes represent the interquartile range, whiskers extend to values within 1.5 times the interquartile range, and individual points indicate outliers. Numbers below the x-axis indicate the number of patients with available DSI scores at each time point.

Table 7E: Short form vascular access questionnaire (SF-VAQ) scores over time by study group

Short form vascular access questionnaire (SF-VAQ)	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Total score					
Predialysis	### (SD ###)	### (SD ###)	###	### (SD ###)	###
- 1 month	### (SD ###)	### (SD ###)		### (SD ###)	
- 2 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 4 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 5 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 7 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 8 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 10 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 11 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis			###		###
- 1 month	### (SD ###)	### (SD ###)		### (SD ###)	
- 2 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 4 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 5 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 7 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 8 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 10 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 11 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Overall satisfaction					
Predialysis	### (SD ###)	### (SD ###)	###	### (SD ###)	###
- 1 month	### (SD ###)	### (SD ###)		### (SD ###)	
- 2 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 4 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 5 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 7 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 8 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 10 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 11 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis			###		###

[illegible]

[illegible]

- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
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Short form vascular access questionnaire (SF-VAQ) scores over time by study group. The questionnaire evaluates four domains of patient access satisfaction: overall satisfaction, physical symptoms, social functioning, and complications. Each item is rated by the patient on a 7-point Likert scale 7 where 7 indicates the highest level of dissatisfaction. Total scores (range 4-28) as well as domain-specific scores were calculated by summing the item scores within each domain. Scores were also linearly transformed to a 0–100 scale for interpretability. Results are presented as mean \pm SD. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized linear mixed models stratified by dialysis status.

Table 7F: Box plots of short form vascular access questionnaire (SF-VAQ) scores over time by study group

Distribution of Short-Form Vascular Access Questionnaire scores over time by study group. Box plots show Short-Form Vascular Access Questionnaire (SF-VAQ) scores at each scheduled measurement occasion, stratified by study group: arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheter (CVC). SF-VAQ scores are presented for the summary score and domain-specific scores, including overall satisfaction, physical symptoms, social functioning, and complications. Scores are transformed to a 0–100 scale for interpretability, with higher scores indicating greater vascular access-related dissatisfaction. The horizontal line within each box represents the median, the boxes represent the interquartile range, whiskers extend to values within 1.5 times the interquartile range, and individual points indicate outliers. Numbers below the x-axis indicate the number of patients with available SF-VAQ scores at each time point.

Table 7G: EQ-5D-5L utility scores over time by study group

EQ-5D-5L utility scores and VAS scores	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Predialysis - Cumulative score			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis – Cumulative score			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - Mobility			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - Mobility			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - Self-care			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - Self-care			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - Usual activities			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	

Dialysis - Usual activities			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - Pain/discomfort			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - Pain/discomfort			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - Anxiety/depression			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - Anxiety/depression			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Predialysis - VAS			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - VAS			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	

EQ-5D-5L utility scores over time by study group. For the five dimensions, each item is scored from 1 to 5, where 1 indicates no problems in that domain and 5 indicates extreme problems or inability to perform the activity. Both total scores across all five dimensions and scores for each individual dimension are reported. The Visual

Analogue Scale (VAS) provides a score from 0 to 100, representing the patient's overall health status, and is reported separately, with higher scores indicating better health. Results are presented as mean \pm SD. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized linear mixed models stratified by dialysis status.

Table 7H: Box plots for EQ-5D-5L utility scores over time by study group

Distribution of EQ-5D-5L scores over time by study group. Box plots show EQ-5D-5L scores at each scheduled measurement occasion, stratified by study group: arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheter (CVC). The five EQ-5D-5L dimensions are scored from 1 to 5, with higher scores indicating more severe problems in that domain. The EQ visual analogue scale ranges from 0 to 100, with higher scores indicating better self-reported overall health. The horizontal line within each box represents the median, the boxes represent the interquartile range, whiskers extend to values within 1.5 times the interquartile range, and individual points indicate outliers. Numbers below the x-axis indicate the number of patients with available EQ-5D-5L scores at each time point.

Table 8A: Vascular access patency outcomes by study group

Vascular access patency	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	Central venous catheter (n= ###)
Primary Patency			
- 6 months	###%	###%	###%
- 12 months	###%	###%	###%
- 24 months	###%	###%	###%
Assisted Primary Patency			
- 6 months	###%	###%	###%
- 12 months	###%	###%	###%
- 24 months	###%	###%	###%
Secondary Patency			
- 6 months	###%	###%	###%
- 12 months	###%	###%	###%
- 24 months	###%	###%	###%
Primary Functional Patency			
- 6 months	###%	###%	###%
- 12 months	###%	###%	###%
- 24 months	###%	###%	###%
Assisted Primary Functional Patency			
- 6 months	###%	###%	###%
- 12 months	###%	###%	###%
- 24 months	###%	###%	###%
Secondary Functional Patency			
- 6 months	###%	###%	###%
- 12 months	###%	###%	###%
- 24 months	###%	###%	###%

Analysis of vascular access patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Patency at different time points is derived from life table analysis.

Definitions for arteriovenous fistulas and grafts

Primary patency: The interval between vascular access creation and the first re-intervention (intervention free vascular access survival) for vascular access dysfunction or thrombosis, the time of measurement of patency or the time of its abandonment. **Assisted primary patency:** The interval between vascular access creation and the first occlusion (thrombosis free vascular access survival) or measurement of patency including operative/endovascular interventions to maintain vascular access. **Secondary Patency:** The interval between vascular access creation and the abandonment of this vascular access (i.e. thrombosis) after one or more interventions or the time of measurement of patency including achievement of a censored event (death, change of haemodialysis modality, loss of follow-up). **Primary functional patency:** The interval between the first use (first cannulation) of a newly created vascular access and the first re-intervention to rescue the vascular access or to its abandonment. **Assisted Primary Functional Patency:** The interval between the first use (first cannulation) of a newly created vascular access and the first occlusion (thrombosis free vascular access survival) or measurement of patency including operative/endovascular interventions to maintain the vascular access. **Secondary Functional Patency:** The interval between the first use (first cannulation) of a newly created vascular access and the abandonment of this vascular access (i.e. thrombosis) after one or more interventions or the time of

measurement of patency including achievement of a censored event (death, change of haemodialysis modality, loss of follow-up).

Definitions for central venous catheters

Central venous catheter interventions not requiring catheter exchange result in loss of primary patency. Central venous catheter exchange (over a guidewire or after a line-free interval) using the same vein results in loss of assisted primary patency and is not considered as vascular access abandonment. Central venous catheter insertion using a different vein is considered as vascular access abandonment and results in loss of secondary patency.

Figure 8B: Kaplan–Meier curves for vascular access patency

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan–Meier curves showing primary patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Numbers at risk at selected time points are shown below the x-axis. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests.

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan–Meier curves showing assisted primary patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Numbers at risk at selected time points are shown below the x-axis. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests.

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan–Meier curves showing secondary patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Numbers at risk at selected time points are shown below the x-axis. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests.

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan–Meier curves showing primary functional patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Numbers at risk at selected time points are shown below the x-axis. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests.

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan–Meier curves showing assisted primary functional patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Numbers at risk at selected time points are shown below the x-axis. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests.

- A. Arteriovenous grafts versus arteriovenous fistulas
- B. Central venous catheters versus arteriovenous fistulas

Kaplan–Meier curves showing secondary functional patency according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Numbers at risk at selected time points are shown below the x-axis. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests.

Table 8C: Time to mature and functional vascular access

	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Time to mature (months)	### (SD ###)				
Time to functional vascular access (months)	### (SD ###)	### (IQR ###)	###	### (IQR ###)	###

Analysis of time to mature and functional vascular access according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. The data are reported as median (interquartile range). The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with log-rank tests on life table analysis.

	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Spontaneous maturation	####% (n= ##)				
Assisted maturation	####% (n= ##)				
Vascular access never functional	####% (n= ##)	####% (n= ##)	###	####% (n= ##)	###
Predialysis patients starting with a CVC	####% (n= ##)	####% (n= ##)	###		

The proportion of spontaneous maturation, assisted maturation, and vascular access failure per study group and the proportion of patients starting haemodialysis with a central venous catheter according to randomized type of vascular access excluding patients with treatment crossover but including patients with treatment non-adherence. Results are presented as counts and percentages. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with Chi squared tests (or with Fisher exact test when the expected cell count was less than 5).

Table 8D: Haemodialysis performance metrics per person year of haemodialysis treatment

Haemodialysis performance metrics per person year of haemodialysis	AVF (... person-years)		AVG (... person-years)		p-value	CVC (... person-years)		p-value
	N	Event rate (97.5% CI)	N	Event rate (97.5% CI)		N	Event rate (97.5% CI)	
Inadequate/impossible dialysis (...-...) (...-...)	### (...-...)	###
Cannulation difficulties (...-...) (...-...)	### (...-...)	###
Cannulation failures (...-...) (...-...)	### (...-...)	###
Central venous catheter dysfunction (...-...) (...-...)	### (...-...)	###

Intention to treat analysis of haemodialysis performance metrics per person year of haemodialysis treatment according to randomized type of vascular access. Cannulation difficulties: More than one attempt was needed to cannulate the vascular access. Cannulation failures: Cannulation of vascular access was not possible. Central venous catheter dysfunction: Blood flow <250 mL/min for ≥30 minutes, or <200 mL/min for any duration. The AVG group was compared to the AVF group and the CVC group was compared to the AVF group using a general linear model with Poisson distribution and identity link, and with time as off-set variable.

Abbreviations: AVF: Arteriovenous fistula. AVG: Arteriovenous graft. CVC: Central venous catheter.

Table 8E: Biochemical markers over time by study group

Serum albumin concentration over time	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Predialysis - Albumin (gr/L)			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 15 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 18 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 21 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 24 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - Albumin (gr/L)			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 15 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 18 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 21 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 24 months	### (SD ###)	### (SD ###)		### (SD ###)	

Intention-to-treat analysis of serum albumin concentration over time according to randomized type of vascular access. Data are presented as means (standard deviations). The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized estimating equations including dialysis status as a covariate.

CRP concentration over time	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Predialysis - CRP (mg/L)			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 15 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 18 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 21 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 24 months	### (SD ###)	### (SD ###)		### (SD ###)	
Dialysis - CRP (gr/L)			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 15 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 18 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 21 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 24 months	### (SD ###)	### (SD ###)		### (SD ###)	

Intention-to-treat analysis of CRP concentration over time according to randomized type of vascular access. Data are presented as means (standard deviations). The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized estimating equations including dialysis status as a covariate.

eKt/V over time	Autologous arteriovenous fistula (n= ##)	Prosthetic arteriovenous graft (n= ##)	p-value	Central venous catheter (n= ###)	p-value
Dialysis - eKt/V			###		###
- Baseline	### (SD ###)	### (SD ###)		### (SD ###)	
- 3 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 6 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 9 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 12 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 15 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 18 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 21 months	### (SD ###)	### (SD ###)		### (SD ###)	
- 24 months	### (SD ###)	### (SD ###)		### (SD ###)	

Intention-to-treat analysis of eKt/V over time according to randomized type of vascular access. Data are presented as mean (standard deviation). The AVG group was compared to the AVF group and the CVC group was compared to the AVF group with generalized estimating equations.

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