RESEARCH PROTOCOL

''The occurrence of abdominal aortic aneurysms in patients with ruptured intracranial aneurysms''

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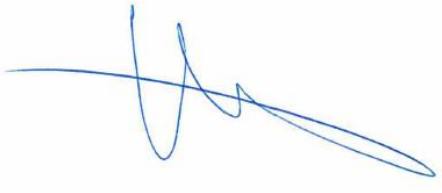
Head of Department: Dr. A. Schepers		14-08-2025
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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

PAA	**Popliteal Artery Aneurysm**
AAA	**Abdominal Aortic Aneurysm**
AA	**Aortic Aneurysm**
CoA	**Coarctation of Aorta**
BAV	**Bicuspid Aortic Valve**
IA	**Intracranial Aneurysm**
aSAH	**Aneurysmal Subarachnoid Haemorrhage**
LUMC	**Leiden University Medical Centre**
SPARTA	**Study on Prognosis of Acutely RupTured Aneurysms**
US	**Ultrasound Duplex**
AE	**Adverse Event**
CCMO	**Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek**
DSMB	**Data Safety Monitoring Board**
GCP	**Good Clinical Practice**
GDPR	**General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)**
IB	**Investigator's Brochure**
IC	**Informed Consent**
IMDD	**Investigational Medical Device Dossier**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
Review committee	**Medical research ethics committee (MREC) or CCMO**
(S)AE	**(Serious) Adverse Event**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
UAVG	**Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG**

WMO **Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Aneurysms of different types are known to be associated. In literature, concomitant concurrence of intracranial- and aortic aneurysms is described. Screening for aortic aneurysms in patients with intracranial aneurysms or aneurysmal subarachnoid haemorrhage could be cost-effective and of significant importance to decrease morbidity and mortality. The available literature on the association between the two types of aneurysms is sparse and in general of poor methodological quality. This protocol presents a study to more adequately evaluate the association between intracranial- and aortic aneurysms.

Objective: To investigate the occurrence of abdominal aortic aneurysms in patients who experienced aneurysmal subarachnoid haemorrhage.

Study design: This prospective cohort study by collaboration of multiple neurovascular centres in the Netherlands will include patients who experienced aneurysmal subarachnoid haemorrhage. The study participants will receive an abdominal ultrasound of the aorta to detect an aneurysm.

Study population: Aneurysmal subarachnoid haemorrhage patients from another prospective cohort trial in the Netherlands.

Main study parameters/endpoints: The primary outcome, is the occurrence of abdominal aortic aneurysms in the here above described study population, detected on abdominal ultrasound.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will not receive an intervention, but only a diagnostic imaging without radiation exposure. The burden associated with this study is considered minimal and the risks negligible. An abdominal ultrasound is a non-invasive diagnostic method with no risks for the participant. The only possible burden to the participant is travel and appointment time with a risk of detecting an abdominal aortic aneurysm or other (occult) intra-abdominal pathologies. When an aneurysm, sub-aneurysm or other intra-abdominal pathology is detected, surveillance or treatment according to standard of care and guidelines will be offered.

1. INTRODUCTION AND RATIONALE

Aneurysms at different anatomical locations are known to be associated with one another and could co-exist (1-3). For example, former research found popliteal artery aneurysms (PAA) and abdominal aortic aneurysms (AAA) to be highly associated, with a co-prevalence of 20-30%(1, 4, 5). Consequently, health care guidelines recommend screening for abdominal aortic aneurysm (AAA) when a popliteal artery aneurysm (PAA) is detected, and vice versa(4). Furthermore, coarctation of the aorta (CoA) and bicuspid aortic valve (BAV) seem to be associated with intracranial aneurysms (IA)(6-8). Due to known associations between different aneurysm locations and the increased prevalence of IA in other aortic pathology, IAs are also suggested to be associated with different types of aortic aneurysms (AA)(3, 9).

Early detection of IAs and AAs is of importance for the prevention of rupture. Aneurysm rupture leads to a major health risk with very high morbidity and mortality(10, 11). Rupture of an AA leads to major intra-thoracic or intra-abdominal bleeding dependent on the type, whereas an IA rupture causes a subarachnoid haemorrhage (aSAH) with a high 30-day mortality and a high risk of neurological complications(12-14). To prevent these severe complications, screening IA patients for AAs or vice versa could be of great relevance.

The available literature on the association between these types of aneurysms is very sparse and of overall low methodological quality(3). For the most part, retrospective- and cross-sectional studies were performed on the question whether IA and AA are associated(15-23). These studies were of low- to moderate methodological quality and with a high variability in IA-AA co-occurrence results. A prospective cohort study from Japan however, which included 181 IA patients, found an AAA-occurrence of 7.2% by ultrasonography(24). Another prospective cohort study from the United States of America found an occurrence of 12% among a study 81 aSAH patients, using ultrasonography as well(25). These occurrence rates are evidently higher compared to the general adult population (0.92-1.31%) and in the male population of 60 years and older (3%)(26, 27). Beside the two mentioned prospective cohort studies in Japan and the United States, research on this subject in the European population is lacking.

Screening for an AAA in IA patients could be favourable for preventing aneurysm rupture. This could lead to less morbidity and mortality, hospital admissions and overall health-care costs. Due to the limited evidence about this subject, it is not yet clear if screening IA patients for AA has a role in daily clinical practice. Earlier research suggests that patients with an IA could be cost-effectively screened for an AAA by abdominal ultrasound (US). Screening for other types of AA or IA in patients with AA is currently thought not favourable, because of the need for other high-cost imaging modalities. The aim of this prospective cohort study is to investigate the occurrence of AAA in patients who have experienced aSAH.

2. OBJECTIVES

Primary Objective: to evaluate the occurrence rate of abdominal aortic aneurysms (AAA) in patients diagnosed with an aneurysmal subarachnoid haemorrhage (aSAH).

Secondary Objective: to detect possible risk factors for the occurrence of AAA in patients who were diagnosed with aSAH.

3. STUDY DESIGN

3.1 Study design

This study will be a prospective cohort study by multiple collaborating centres in the Netherlands.

During the period of the study, all aSAH patients (from another prospective cohort trial) will be screened for inclusion eligibility. Eligible patients will be included as subjects in this study. Study subjects will receive an abdominal US focused on the abdominal aorta. Detecting an AAA on abdominal US will result in the daily standard of care for AAA, including surveillance and possible treatment by medication, intervention or surgery.

4. 3.2 Study sites

This study will be conducted by the Department of Surgery in the main study location University Medical Center Leiden (LUMC) in collaboration with University Neurosurgical Center Holland (UNCH). Eligibility screening and inclusion will be performed by the LUMC.

To answer the research questions of this study, one abdominal US to measure the diameter of the aorta will be performed on the included patients.

3.3 Number of study subjects

We will include 233 subjects as one single cohort. In this study, the collected data and analysis will be compared to the general- and at-risk population.

3.4 Study duration

During an initial period of 6 months, patients will be included as study subjects. Inclusion stops when the targeted number of study subjects (N=233) is reached. The study duration is expected to be around 1.5 years and the study period will end when all 233 study subjects had an abdominal US, or were excluded from the study during the study period for particular reasons.

5. STUDY POPULATION

5.1 Population

All aSAH patients from another large prospective cohort trial in the Netherlands will be screened for eligibility(12). The Study on Prognosis of Acutely RupTured Aneurysms (SPARTA) is an observational prospective cohort trial conducted in the Netherlands in several neurovasculair centres. The aim of this study was to evaluate the long-term clinical outcome of aSAH patients who underwent neurosurgical- or endovascular treatment for their ruptured IA. The study has a population of around 900 patients. Because of the high risk of morbidity following aSAH, a large proportion of this study population will be diseased or heavily incapacitated.

5.2 Inclusion criteria

Patients with a modified Ranking Scale (mRS) of 0-2 will be screened for inclusion eligibility in this study(28). This patient group will have the most potential benefit when an AAA is detected, due to being still functionally and cognitively independent and longer survival. Since patients with an mRS of 3 also have a relatively good outcome compared to patients with an mRS of 4-6, these patients might be included as well. Patients with an mRS of 4 until 6 are severely impaired in their functional and cognitive performance and therefore highly dependant on medical care after aSAH. Furthermore, mRS of 6 means that the patient is deceased. In terms of already existing morbidity and mortality in this proportion of the aSAH patient population, inclusion of those patients would be less relevant for this study aim.

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

- Patient is a study subject of the already existing trial: Study on Prognosis of Acutely RupTured Aneurysms (SPARTA)(12)
- Inclusion at least one year after aSAH
- Written informed consent

By being a study subject of the SPARTA trial, the following criteria are applicable:

- Confirmed diagnosis of SAH on CT-scan or lumbar puncture (in the presence of a negative CT-scan)
- IA related SAH as confirmed with radiological imaging
- Age 18 years or older at presentation
- Written informed consent for the SPARTA-trial

5.3 Exclusion criteria

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

- Patient has Loeys-Dietz-, Marfan- or Ehlers-Danlos syndrome
- Patients with an mRS of 4 until 6

5.4 Sample size calculation

Calculation of sample size was performed by using the population-wide prevalence rates of AAA in IA patients. The occurrence rate of AAA will be determined in the study population of this study.

As formerly described, in the general population, a prevalence of 0.9% for AAA has been found. The prevalence of AAA in the at-risk group (men over 60) varies across earlier studies but is most often reported between 2 and 3%. For this study, the upper bound - a prevalence of 3% - was assumed in the ‘known population’ for comparison.

The population of this study is expected to be comparable to study populations of other prospective studies on this matter, which report a high occurrence rate of 7–12% for AAA. Therefore, an occurrence rate of 7% was assumed in the population in this study, which

represents the lower bound of the anticipated occurrence rate. Using these assumptions in a single-group design to obtain a two-sided 95% confidence interval, we require a sample size of 233 patients.

6. TREATMENT OF RESEARCH PARTICIPANTS

Not applicable, since no treatment will be performed in this study.

7. INVESTIGATIONAL PRODUCT

Not applicable, since no product will be tested in this study.

8. NON-INVESTIGATIONAL PRODUCT

Not applicable.

9. METHODS

9.1 Main study parameter/endpoint

The primary endpoint of this study will be the occurrence rate of AAA in the study population. This occurrence rate will be calculated as the proportion of all performed US in the study group (N; %).

9.2 Secondary study parameters/endpoint

As a secondary endpoint, we will evaluate risk factors of having an AAA as an aSAH patient. Presence of these factors (i.e. smoking, aneurysmal disease in medical history, age, gender) will be calculated as the proportion of the total study population (N; %).

9.3 Randomisation, blinding and treatment allocation

Not applicable in this study, since this will be a prospective single-cohort study using diagnostics and no treatment modalities.

9.4 Study procedures

The study procedures will be performed at LUMC. Informed consent will be obtained from the coordinating- and local investigator. When informed consent is obtained from the patient, inclusion starts and the study subject will be invited for an US examination of the abdominal aorta.

The abdominal US will be performed 1 year after aSAH. The examination will be performed by experienced ultrasonographists. The abdominal aorta in a study subject will be defined as AAA when having a diameter of 30 millimetres or more is measured. The region in which the abdominal aorta will be measured is from the celiac trunk until the aortic bifurcation.

Detailed data from the US examinations (including aneurysm diameter, morphology and specified location) will be collected and stored in an electronic data centre (Castor EDC). Additional data, including medical history, gender, and more, will be collected as well.

Data analysis will be centralized and performed by the coordinating investigators of this study.

Nota Bene: when an AAA is detected on abdominal US, this needs to result in the current standard of care for AAA. The study subject will receive a letter about the findings of the US, which will be sent to their general practitioner. A referral to a vascular surgeon can consequently be made. When a sub-aneurysm is found, defined as the aorta having a diameter of 25-29 millimeters, this will result in a letter to the general practitioner as well with an advised follow-up by US every 5 years. This is according to the guidelines of the European Society of Vascular Surgery (ESVS)(29).

9.5 Timing of data acquisition

Baseline

- Informed consent form
- Baseline information Case Report Form (CRF)
- Baseline information includes relevant medical history, medication, smoking.

Ultrasound Centre

- Diameter measurement of the abdominal aorta
- Location of the aneurysm (i.e. suprarenal, juxtarenal or infrarenal)
- Morphology of the aneurysm (i.e. saccular or fusiform)
- Involvement of the mesenteric-, renal-, lumbar- or iliac arteries

9.6 Withdrawal of individual research participants

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

9.7 Premature termination of the study

This is not applicable since there are no significant risks for the patients, which could lead to such termination of this study.

10. SAFETY REPORTING

10.1 Temporary halt for reasons of research participant safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise participant health or safety. The sponsor will notify the review committee without undue delay of a temporary halt including the reason for such an action. It is noted that such is not to be expected form this study, as has been explained in paragraph 9.6.

10.2 AEs, SAEs

10.2.1

Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a participant during the study, whether or not considered related to examination. The study subjects will undergo merely one US during this study, which is a non-invasive imaging modality. However, it is crucial to warrant the safety of the study subjects. Therefore, the adverse events reported by the participant or observed by the investigator or his staff only during the abdominal US examination of this study will be recorded. The same will apply for SAEs, described in paragraph 10.2.2.

10.2.2

Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The sponsor will only report the SAEs during the US examination. These reports will be sent through the web portal *Research Portal* to the review committee that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum 8 days to complete the initial preliminary report.

10.3 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.
SAEs will be reported till end of study.

10.4 Data Safety Monitoring Board

As has been previously explained in this study protocol, no risk in safety of the study subjects is expected. The actions on the study subjects consist solely of one abdominal US, which is a non-invasive imaging procedure. Therefore, no Data Safety Monitoring Board or Safety Committee is needed for this study.

11. STATISTICAL ANALYSIS

Data analyses are primarily descriptive. Categorical variables are reported as frequency (N) and percentage (%). Continuous variables are reported as mean and standard deviation or

median and interquartile range (IQR), based on the normality of the distribution. For categorical variables, odds ratios will be calculated with corresponding 95% confidence intervals. For continuous variables, the mean difference is calculated with corresponding 95% confidence interval. Statistical comparisons are performed with χ^2 test or Fisher's exact test for categorical variables and Student's *t*-test or the Mann-Whitney U test for continuous variables.

Men of age more than 65 years old are known to have a higher risk of developing an AAA compared to other groups. Therefore, a possible subgroup analysis will be performed in comparison to other patients.

To identify independent predictors for having an AAA as aSAH patient, multivariate analyses through binary logistic regression models with corresponding 95% confidence intervals will be performed. Possible confounders of the relation between aSAH and AAA (i.e. age, history of hypertension, smoking, sex) are added as covariates.
Analysis will be performed in R and in the Statistical Package for the Social Sciences (SPSS) version 21. A p-value < 0.05 will be considered statistically significant.

12. ETHICAL CONSIDERATIONS

12.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO).

12.2 Recruitment and consent

Patients form the SPARTA-trial will be asked to participate in this study one year after aSAH and will be informed of the study procedures and possible risks. When informed consent is obtained, data collection will start and an abdominal US will be performed.

Written informed consent will be obtained from the patient. Information about the study will be given both verbally and in writing. After a pre-specified time for consideration, the informed consent form will be signed by the patient and the investigator.

When a study subject withdraws from their consent for the study before the abdominal US is obtained, no data will be used. When the US has already been obtained, then all data up to the moment the study subject withdrew consent will be used for analysis.

12.3 Compensation for injury

The investigators have asked for exemption for an insurance for research subjects and compensation for injury, since only one abdominal US will be performed and for the rest no other actions are applied to the study subjects. There exist no risk of injury or death in performing an abdominal US.

13. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

13.1 Handling and storage of data and documents

All data will be treated confidentially, coded and will be registered on data registration forms. Data management will be handled at the Division Vascular Surgery of Leiden University Medical Center. Data will be stored in an electronic data capture and management system. Imaging data from the performed US will be stored separately in a picture archiving and communication system at the main study centre. A list that contains the study participant and associated study identification code will be used to identify an individual study participant if necessary. This identification code will not be based on the participants initials or date of birth. The list that links the study identification code to the study participants will be kept on a designated partition on the hard drive of the research centre. This part will be protected by a password. People who have access to this partition are local researchers and quality monitor appointed by the principal investigator. These procedures comply with the European law: Algemene verordening gegevensbescherming (AVG). All raw data will be collected and stored at the main study site, including the trial master file, investigator site file, informed consent forms, study data and imaging data. The acquired data will be stored for 15 years after the study is finished and will be used for further research if the participant has provided consent for the data to be used in further studies.

13.2 Monitoring and Quality Assurance

Data monitoring and quality assurance will be handled by the Directorate of Quality and Patient safety (DKP) at LUMC. Study monitoring will be performed once during the expected study period of 1.5 years. We will monitor the informed consent forms, the investigator site file and the trial master file, as well as the collected data from the CRF and the abdominal US.

13.3 Amendments

Amendments are changes made to the research after a favourable opinion by the review committee has been given. All amendments will be notified to the review committee that gave a favourable opinion.
Non-substantial amendments will not be notified to the review committee, but will be recorded and filed by the sponsor.

13.4 Annual progress report

The sponsor/investigator will submit one summary of the progress of the trial to the review committee after one year. Information will be provided on the date of inclusion of the first participant, numbers of participants included and numbers of participants that have completed the trial, serious adverse events, other problems, and amendments. No more progress reports will be made, since the total study duration is expected to be 1.5-2 years.

13.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the review committee of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient who underwent his or her ultrasound duplex.

The sponsor will notify the review committee immediately of a temporary halt of the study, including the reason of such an action.
In case the study is ended prematurely, the sponsor will notify the review committee within 15 days, including the reasons for the premature termination.
Within two years after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the review committee.

13.6 Public disclosure and publication policy

This study protocol will be published online, and the study will be registered in an online trial register. After data analysis, these will be published in a peer-reviewed journal. All publications using data generated by this study should be discussed and agreed upon by the investigators and sponsor.

14. STRUCTURED RISK ANALYSIS

Not applicable.

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