DART Study Protocol



Frank-David Øhrn, Nordmøre and Romsdal Hospital (SNR), Møre and Romsdal Hospital Trust 2026

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1. STUDY SYNOPSIS

Topic	Details
Project leader	Frank-David Øhrn, MD, PhD
Study name	Day-case Arthroplasty in Møre and Romsdal Trial
Study acronym	DART
Study Design:	Prospective observational multicentre study
Duration of Study:	Approximately 12 months inclusion and 3 months follow-up. In total 15months.
Indication	Primary elective total hip arthroplasty (THA), unicompartmental knee arthroplasty (UKA), total knee arthroplasty (TKA).
Follow-up period:	3 months.
Study locations:	Møre og Romsdal Hospital Trust (MRHT): Nordmøre and Romsdal Hospital (SNR), Volda Hospital and Ålesund Hospital
Number of Subjects:	210 patients (TKA and THA combined)
Study Population:	Inclusion: Patients aged 18-80 years undergoing unilateral primary TKA, UKA or THA, ASA physical status 1-2, and 3 after individual evaluation by anaesthesiologist, and able to provide written informed consent. Exclusion: Not motivated for day-case surgery, lack of an adult caregiver staying with the patient for the first 24 hours post-discharge, ASA physical status III (if not approved by anesthesiologist) and IV, travel distance to acute hospital no more than 1 hour (ferry-free), dementia or other reasons for lacking compliance (e.g., substance abuse, severe psychiatric disease etc), BMI > 40, Clinical Frailty Scale (CFS) >3, previous or ongoing chronic pain disorder or regular preoperative opoid anelgetics therapy.

Treatment Groups:	2 treatment groups (TKA/UKA and THA)
Primary endpoint:	Proportion of same day discharge (SDD)
Secondary endpoints:	Quality of Recovery-15, Numerical rating scale (NRS), Patient reported outcome measures (PROMs): KOOS, HOOS, FJS), EQ-5D, pain (NRS), complications, Clavien-Dindo grading and Comprehensive Complication Index (CCI®), readmissions, return to work, cost data, radiographs, operation time (minutes), estimated blood loss during surgery (mL).
Randomization:	No randomization
Overall aim:	The overall aim of the DART Study is to assess the implementation, clinical and patient reported outcomes, and safety through a standardized day-case pathways for patients undergoing primary hip and knee arthroplasty with particular focus on the proportion of patients achieving same-day discharge.
Primary hypothesis:	In a standardized day-case pathway supported by multimodal analgesia including postoperative femoral triangle block (FTB) and genicular nerve blocks (GNB) for knee procedures and pericapsular nerve group block (PENG) for hip procedures, for primary THA and TKA, the proportion of patients successfully discharged on the day of surgery (SDD) will be high (>80%) demonstrating feasibility of day-case arthroplasty in Møre and Romsdal.
Secondary (safety) hypothesis	High SDD rates will be achieved without an unacceptable increase in 30-day readmissions or serious adverse events plausibly related to same-day discharge and early postoperative management.
Visit Schedule:	1 day (telephone), 1 week (telephone and/or digital), 1 month (telephone and or digital) and 3 months (physical, telephone and or digital) after surgery.

Safety Assessments:	If any unforeseen complication occurs outside normal clinical practice that is plausibly related to the same-day discharge pathway, the sponsor (i.e., the project leader) will be notified as soon as possible. In such cases, the reference group will be consulted for safety assessment and to evaluate whether corrective actions are required, including potential protocol modifications or, in the most severe cases, temporary study suspension. Safety data will be systematically collected at each follow-up using a predefined CRF documenting complications, readmissions, and other safety outcomes.
Overview of Statistics:	The primary outcome of the DART study is proportion of successful SDD. The analysis will estimate the proportion of patients achieving SDD in the total cohort and stratified by procedure type (TKA vs. THA). Continuous baseline variables will be assessed for normality. Normally distributed variables will be presented as means and standard deviations (SD), while non-normally distributed variables will be reported as medians and interquartile ranges (IQR). Categorical and dichotomous variables will be summarized as counts and percentages. Baseline characteristics will be reported for the total cohort and stratified by procedure type (TKA/UKA vs. THA).
Sample Size:	The primary objective is to estimate the proportion of patients achieving same-day discharge following standardized day-case hip and knee arthroplasty. With a sample size of 210 patients, we expect to be able to estimate this proportion with a margin of error of +/- 5-6 percentage points.
Interim Analysis:	An interim analysis on the proportion of SDD, readmissions and complications will be performed 7 months after FPI (6 months plus 1 month follow up).

Monitoring Plan:	N/A
Study stopping rules:	Inclusion of 105 TKAs *and* 105 THAs, or 1.5 years after study start, whatever happens first.
End of study:	The end of this study is 3 months after the last included patient.
Estimated cost of study:	Full PhD scholarship (3 years 100% position) financed by Central Norway Regional Health Authority (RHA), and study nurse 30% position as long as the study runs financed by MRHT. Running costs outside this will be applied for as needed.
Operational risk analysis:	Inability to include 210 patients (TKA and THA) within 12 months years may prolong the inclusion period.
Study target dates:	Please see table below.

Milestone	**Study Timeline: Target Date (Month/Year)**
First Patient In (FPI)	October 2026*
Last Patient In (LPI)	October 2027**
Last Patient Out (LPO)	January 2028
Database Lock (DBL)	January 2028**
First Look (FL)	April 2027***

Table 1* FPI will be as soon as possible after final approval of the study. **May be extended up to 6 months if the recruitment target has not been reached. ***6months after FPI.

Brief Investigator Biography	
Frank-David Øhrn	Senior consultant orthopaedical surgeon, researcher, project leader, main supervisor, MD PhD, Nordmøre and Romsdal Hospital (SNR), Norwegian university of science and technology (NTNU)
Tommy Frøseth Aae	Consultant orthopaedical surgeon, research group leader, co-supervisor, MD PhD, SNR, NTNU
Kirsti Sevaldsen	Senior consultant orthopaedical surgeon, head of orthopaedic section SNR, Associate professor NTNU, co-supervisor, MD, PhD, SNR
PhD candidate	Erik Ostnes, Senior consultant orthopaedical surgeon, Volda Hospital, MRHT.

2. SHORT SUMMARY

The DART Study is a prospective multicentre clinical trial evaluating the proportion of same day discharge (SDD), readmissions, complications, recovery, feasibility, safety, and outcomes of day-case total hip arthroplasty (THA), total knee arthroplasty (TKA), and unicompartmental knee arthroplasty (UKA) across three acute hospitals in Møre and Romsdal. Using standardized fast-track pathways with multimodal analgesia including femoral triangle block (FTB) and genicular nerve blocks (GNB) for knee procedures and pericapsular nerve group (PENG) blocks for hip procedures, the study primarily investigates proportion of same day discharge (SDD) and early recovery. The project is designed as an integrated PhD project with three complementary components: (1) a main clinical outcomes study assessing proportion of SDD, readmissions, complications, functional recovery, pain, and patient-reported outcomes; (2) a qualitative study exploring patient experiences and perceptions of day-case arthroplasty through semi-structured interviews and (3) a registry based study with Norwegian Arthroplasty Register (NAR) and National Patient Registry data comparing inpatient and day-case arthroplasty surgery. The project will also perform an SNR early implementation cohort-quantitative evaluation and decision criteria for transfer of day-case arthroplasty. Together, these components will provide a comprehensive evaluation of safety, clinical effectiveness, patient-centred outcomes and experiences to inform future implementation and scaling of regional and national day-case arthroplasty.

3. INTRODUCTION

Day-case hip and knee arthroplasty has gained increasing attention as advances in fast-track perioperative pathways have demonstrated that same-day discharge can be achieved safely in selected patients. Early work consistently showed that modern multimodal analgesia, early mobilisation and standardized discharge criteria enable shorter length of stay without increasing complications or readmissions (1).

Recent studies have further strengthened the evidence base by documenting favourable safety profiles, high patient satisfaction and predictable recovery trajectories when same-day discharge is implemented in routine clinical practice (2). Importantly, newer analyses emphasise the central role of optimized pain control as a prerequisite for functional discharge, particularly after total knee arthroplasty (TKA), where pain remains a major barrier to mobilization and recovery (3). Peripheral nerve blocks in terms of pericapsular nerve group (PENG) block, femoral triangle block (FTB) and genicular nerve blocks (GNB) may play an important role in multimodal pain management (4-8).

Large data sets from fast-track arthroplasty programs further support that early postoperative pain trajectories differ between procedures, with knee arthroplasty associated with higher pain intensity and greater opioid consumption than hip arthroplasty during the first 24 hours findings highly relevant when designing day-case pathways (3).

Nevertheless, we know that day-case hip and knee arthroplasties with careful selection of patients are safe and not associated with increased healthcare contacts postoperatively (9, 10).

Despite this progress, real-world evidence from multicentre regional implementations remains limited. There is a need for pragmatic studies evaluating discharge success, safety, recovery, pain management and functional outcomes when day-case hip and knee arthroplasty is introduced across an entire hospital region, and optimized with multimodal analgesia including nerve blocks in all patients. To our knowledge, no studies on day-case arthroplasty surgery do consistently make use of peripheral nerve blocks as their multimodal pain management (2, 9). This is a possible gamechanger that might increase the proportion of SDD significantly. Further, there is a lack of evidence from patient perspectives. The DART Study aims to address these knowledge gaps. The study is named the DART Study (Day-case Arthroplasty in Møre and Romsdal Trial) to emphasize that careful patient selection is critical for safe and successful day-case arthroplasty, as outcomes depend on identifying patients with sufficient physiological reserve and support for same-day discharge.

This project was initiated by the Minister of Health and Care Services in Norway, among other reasons, to evaluate whether the reintroduction of day-case arthroplasty at SNR Kristiansund would be feasible and safe, or not.

The overall aim of the DART Study is to assess the implementation, clinical and patient reported outcomes, and safety through standardized day-case pathways for hip and knee arthroplasty across multiple hospitals with a special focus on proportion of same day discharge (SDD). This information will then be used to evaluate the potential reintroduction of day-case TKA and THA surgery in a clinical setting without the possibility of overnight stay or acute surgical interventions (i.e. SNR Kristiansund)

The sub-aims are the following:

- To quantify early functional recovery, pain, rehabilitation and complications after day-case THA, TKA, and UKA.
- To explore patients' experiences, expectations, and perceived safety of day-case arthroplasty through qualitative interviews.
- To evaluate the surge of national THA, TKA and UKA day-case surgeries and assess the number of potential readmissions and complications related to that.

4. RESEARCH DESIGN

The main study of the DART is multicentre observational cohort study with standardized treatment pathway applied across all hospitals in Møre og Romsdal Hospital Trust (MRHT, i.e. SNR, Ålesund and Volda Hospitals). Data collection at baseline, perioperative, 24h, 1 week, 1 month and 3 months.

5. MATERIALS AND METHODS

5.1 Scheduling of cases

All day-case surgeries will be scheduled as patient number 1 of the day. If more than 1 day-case patients are planned at the same operating theatre, they will be scheduled as number 1 and 2 for the day. Any inpatient surgeries on the same day and theatre will be scheduled subsequently.

5.2 Recruitment and screening for day-case eligibility

5.2.1 Primary screening and recruitment pathway

All patients scheduled for primary prosthetic surgery (THA, TKA, UKA) in MRHT will be screened for eligibility for day-case arthroplasty using a dedicated screening form, where reasons for non-eligibility are also recorded. This will be performed at the outpatient clinic, where patients receive written and oral information of the study. A study nurse will then call the patients within 1-2 weeks to check if the information is understood, and the patient wants to participate.

5.2.2 Secondary screening and recruitment pathway

If for some reason, screening for eligibility has not been performed at the time of surgical listing, screening and subsequent written and oral information will be given to the patients at least a week before the preoperative clinic, so that the patients are well informed and can make their potential well-informed written consent at the preoperative clinic 1–2 weeks prior to surgery. If screening indicates that day-case surgery is feasible, the final approval must be given by the operating surgeon and the responsible anaesthesiologist. The secondary recruitment pathway is important in order to secure that we have a valid estimate of proportion of eligible patients in the study, especially in the beginning of the study period.

5.3 Collection of data

Variable	CP1 Baseline (Prepol)	CP2 Surgery day (pre-discharge)	CP3 POD1 (phone)	CP4 1 week	CP5 1 month	CP6 3 months
Demographics / baseline data	X					
Operative & perioperative data		X				
NRS pain	X	X	X	X*	X	X
KOOS/ HOOS	X					X
Forgotten Joint Score (FJS)	X					X
EQ-5D	X					X
QoR-15nor	X	X	X	X**	X	X
Complications / SAE		X	X	X	X	X
Anchoring questions				X	X	X

Table 2 *Table of the collection of variables at different checkpoints (CP). Variables at CP1 will be collected at the preoperative information day, CP 3 on phone by clinical staff at the daycare unit at each hospital postoperative day 1 (POD1), CPR 4 and CP 5 per phone or digitally (EPROMs) by research coordinator, CP6 either by personal meeting*

*or by phone/digitally. *NRS (numeric rating scale) pain each postoperative consecutive day the first 7 days with worst and best recording during each day and QoR15nor** at postoperative day 3 and 7 collected at CP4. HOOS= Hip disability and osteoarthritis outcome score, KOOS= Knee injury and osteoarthritis outcome score. SAE= Serious adverse events*

5.4 Participants

Inclusion criteria	
	Patients 18-80 years old scheduled for primary THA, TKA or UKA in MRHT
Exclusion criteria	
	Patient not motivated for day-case surgery Lack of an adult caregiver staying with the patient for the first 24 hours post-discharge. ASA class III* (if not approved by anesthesiologist) and IV Travel distance to acute hospital no more than 1 hour (ferry-free) Dementia or other reasons for lacking compliance (e.g., substance abuse, severe psychiatric disease etc) BMI > 40 Patients with anticipated high level of pain after surgery due to previous experience, comorbidity (i.e. chronic pain syndrome, fibromyalgia) or regular preoperative opoid anelgetics therapy

Table 3 Inclusion and exclusion criteria. Møre and Romsdal Hospital Trust (MRHT). American Society of Anesthesiologists (ASA) Classification System. Body mass index (BMI). *Norwegian standard for anaesthesiology (11)

5.5 Preoperative pain management

Preop analgesics	
	Paracetamol tbls 1.5–2 g[1,2] Etoricoxib tbls 90–120 mg[1,3] Dexamethasone tbls 24 mg[4] Tapentadol depot tbls 50 mg[5]

Table 4 Per oral pain management 1 hour prior to surgery. [1] <60 kg ***or*** >70 years : 1.5 g Paracetamol and 90 mg Etoricoxib, patients 60kg > ***and*** < 70 years : 2 g Paracetamol and 120 mg Etoricoxib. [2] Anatomic Therpeutic Chemical Classification system (ATC) numbers N02BE01, [3] M01AH05, [4] H02AB02 and [5] N02AX06 respectively.

5.6 Interventions

5.6.1 Knee anaesthesiologic procedures

All TKA and UKA procedures in the DART study are performed with spinal anaesthesia. Anatomic Chemical Classification system numbers (ATC) in brackets:

SNR: Mepivacaine (Carbocaine, N01BB03) 20 mg/mL: 3.0-4.0 mL

Ålesund Hospital: Bupivacaine (Marcaine, N01BB01) 5 mg/mL: 2.5-3.0 mL

Volda Hospital: Prilocaine (Takipril, N01BB04) 20 mg/mL: 3.5-4.0 mL

All TKA and UKA procedures will receive postoperative FTB: Ropivacaine 5 mL 5 mg/mL (N01BB09) 10-12 mL, the following GNB: superior lateral genicular nerve (SLGN), superior medial genicular nerve (SMGN) and inferior genicular nerve (INGN), Ropivacaine 3.75 mg/mL total of 12-15 mL and block for the nerve to the Vastus Intermedius: Ropivacaine 3.75 mg/mL 4-5 mL, ultrasound guided by anaesthesiologist. Infiltration between the Popliteal Artery and Capsule of the Knee (IPACK) is performed by the surgeon during surgery using a mixture of Ropivacaine 100 mL 2mg/mL, Fentanyl (N01AH01) 1 mL 0.05 mg/mL and Adrenaline (C01CA24) 0.5mL 1mg/mL.

5.6.2 Hip anaesthesiologic procedures

Spinal anaesthesia corresponding to 5.6.1. All THA procedures also receive postoperative PENG block with Ropivacaine 15–20 mL 5 mg/mL. Lateral femoral cutaneous nerve block (LFCN): Ropivacaine 5 mL 5mg/mL when suited according to site of surgical incision.

5.6.3 Intraoperative Management

Propofol (ATC N01AX10) sedation as needed, Target Controlled Infusion 1–1.5 µg/mL, discontinuation post-surgery.

5.7 Operative Procedures

5.7.1 Knee procedures

Manual or robotically assisted TKAs and UKAs are performed using a medial parapatellar approach. TKA with or without patella resurfacing, with or without eversion patella. Mechanical or personalized alignment philosophies will we applied.

5.7.2 Hip arthroplasty

THAs are performed using either anterior or posterior approach.

5.8 Postoperative pain management

Medications given at the daycare unit or the postoperative care unit:

Postoperative analgetics	
	Paracetamol[1] 1 g x 4
	Oxycodone[2] 2.5 mg perorally or 5 mg tablets as needed
	Tapentadol[3,4] depot 50-100 mg

Table 5 Per oral pain management. ATC numbers [1]N02BE01, [2] N02AA05, and [3]N02AX06 respectively. [4] 50 mg if patient is >70 years ***or*** <60 kg ***and*** 100 mg if patient is < 70 years and > 60 kg 100 mg (single dose).

5.9 Discharge pain management

Medications given upon discharge:

Discharge analgetics
Paracetamol[1] 1 g x 4
Etoricoxib[2,3] 60–90 mg x1
Tapentadol[4] depot 50 mg x 2 for 5 days
Oxycodone[5] 5 mg perorally up to 6 times a day as needed

Table 6 Per oral pain management. ATC numbers [1]N02BE01,[2]M01AH05, [4]N02AX06 and [6]N02AA05 resepcetively. [3]60 mg for patients >70 years or <60 kg and 90 mg for patients < 70 years and > 60 kg, 1 tablet per day up to 28 days

5.10 Discharge criteria

We follow a modification of previously published criteria for SDD (12):

Activity level
Steady ambulation with crutches. Particular attention should be paid to THA patients who have received a PENG block No dizziness during mobilization Can use stairs, if required by patients´ home environment
Postoperative nausea and vomiting
Minimal and efficiently treated with or without medication. NEWS* < 2 Patients with NEWS >= 2 must be discussed with a doctor prior to discharge
Vital signs
Must be stable and consistent with age and preoperative baseline values. Systolic blood pressure within 20 mmHg of preoperative levels. Oxygen saturation > 95%. Resting pulse < 100 bpm.
Pain
NRS < 3 at rest NRS < 5 when walking 5 metres Or otherwise, acceptable level of pain assessed by the patient, regardsless of NRS
Postoperative bleeding
Should be consistent with expected blood loss for this procedure and not require repeated dressing change. Patients should be hemodynamically stable (no tachycardia (resting pulse >100 bpm) or hypotension (SBP <100 mmHg)) and should not show clinical signs of anemia (pallor, dizziness during mobilization, or fatigue).

Table 7 Criteria for discharge published by Lindberg-Larsen (12). NEWS = National Early Warning System 2 (13)

If the discharge criteria are met, the nurse at the day surgery unit can discharge the patient after the performing surgeon has informed the patient. If any doubt exists, the responsible anesthesiologist takes the decision on whether the patient should be discharged or admitted to hospital.

6. VARIABLES

6.1 Demographics

Age, sex (male/female), Body Mass Index (BMI), comorbidities, American Society of Anesthesiologists (ASA) Physical Status Classification System, Clinical Frailty Scale (CFS) (14) , medications, joint (hip/knee), operation side (left/right) blood samples (Hb, CRP, LPK etc), employment status, educational degree, previous hip or knee surgery etc.

6.2 Primary outcome measure

Proportion of SDD of the whole cohort (TKA and THA) at the day of surgery

6.3 Secondary outcome measures

Quality of Recovery-15 (15, 16) , Clavien-Dindo grade and Comprehensive Complication Index (CCI®) (17), Numerical rating scale (NRS) (18), knee injury and osteoarthritis outcome score (KOOS) (19), Hip disability and Osteoarthritis Outcome Score (HOOS) (20), Forgotten Joint Score (FJS) (21) , EQ-5D-5L (22), complications, readmissions, return to work, cost data, radiographs (Kellgren & Lawrence radiologic classification) (23), operation time (minutes), estimated blood loss during surgery.

7. STATISTICS AND SAMPLE SIZE

7.1 Primary outcome

The primary outcome of the DART study is proportion of successful SDD of the whole cohort, defined as discharge to home on the day of surgery. The analysis will also estimate the proportion of patients achieving SDD by procedure type (TKA vs. THA).

The choice of SDD as the primary outcome reflects its relevance as a feasibility measure, as previous studies of day-case arthroplasty have not consistently incorporated peripheral nerve blockade as a standardized component.

7.2 Descriptive statistics and baseline data

Continuous baseline variables will be assessed for normality. Normally distributed variables will be presented as means and standard deviations (SD), while non-normally distributed variables will be reported as medians and interquartile range (IQR).

Categorical and dichotomous variables will be summarized as counts and percentages. Baseline characteristics will be reported for the total cohort and stratified by procedure type (hip vs knee arthroplasty).

7.3 Comparative analyses of SDD

Proportions of patients achieving SDD will be compared between hip and knee arthroplasty using chi-square tests or Fisher's exact test, as appropriate. Effect estimates will be presented as risk ratios (RR) or odds ratios (OR) with 95% confidence intervals.

To account for potential confounding, multivariable logistic regression will be used to evaluate the association between procedure type (THA vs TKA) and SDD, adjusting for relevant baseline variables such as age, sex, BMI, ASA classification, and/or other clinically relevant covariates. A directed acyclic graph (DAG) will be constructed to define the assumed causal structure between treatment pathway (THA vs TKA), patient characteristics, institutional factors, and outcomes. The DAG will guide identification of a minimally sufficient adjustment set to reduce confounding while avoiding adjustment for mediators or colliders. Because the spinal anesthesia differs between the hospitals, this will be seen as an explorative covariate.

7.4 Readmissions within 30 days

Readmissions within 30 days postoperatively will be analyzed as secondary outcomes and classified into:

1. All-cause readmissions, and
2. Readmissions plausibly related to the same-day discharge pathway, including complications potentially attributable to early discharge or early postoperative management.

Readmission rates will be reported as proportions and compared between hip and knee arthroplasty using chi-square tests or Fisher's exact test, as appropriate. Separate multivariable logistic regression models will be constructed for all-cause and pathway-related readmissions, with procedure type as the primary predictor and adjustment for

relevant baseline covariates. Given the expected low event rate for readmissions, adjusted analyses will be interpreted cautiously and primarily considered exploratory.

7.5 Relationship between SDD and readmission

To explore the safety of SDD, additional analyses will assess the relationship between SDD and 30-day readmissions:

- Readmission rates will be compared between THA and TKA among patients successfully discharged on the day of surgery.
- Logistic regression models may include SDD status as a covariate to evaluate its association with readmission and to explore potential interaction effects between procedure type and SDD status.

7.6 Repeated measures and longitudinal analyses

Repeated measurements of patient-reported outcome measures (PROMs), including numerical rating scales (NRS), will be analyzed using linear mixed models. Time will be included as a fixed effect, with procedure type (THA vs. TKA) as a grouping variable. Interaction terms between time and procedure type will be used to assess differences in postoperative trajectories. Random intercepts for patients will be included, and random slopes for time will be considered where appropriate.

7.7 Handling of missing data

Missing data will not be imputed for descriptive analyses. Longitudinal analyses using mixed-effects models inherently accommodate missing observations under the missing-at-random assumption.

7.8 Sample size considerations

The primary objective is to estimate the proportion of patients achieving same-day discharge following standardized day-case hip and knee arthroplasty, rather than to test a predefined treatment effect. With a sample size of 210 patients, and a hypothesized proportion SDDs of around 80% we are able to estimate the proportion of SDDs with a margin of error of +/- 5-6 percentage points.

All consecutive eligible patients undergoing planned day-case hip or knee arthroplasty during a predefined inclusion period of approximately 12 months will be included. This pragmatic approach is expected to provide sufficient precision for estimating discharge success and to allow exploratory comparative and longitudinal analyses. However, according to the Norwegian Arthroplasty Register, MRH performed a combined number

of 1044 and 850 hip and knee arthroplasties in 2023 and 2024 respectively (24, 25). With a conservative estimate of 30% eligible patients, we aspire to recruit 210 (105 TKAs and 105 THAs) patients within the inclusion period. To account for potential differences between the hospitals, it is an objective, but not an explicit requirement, that each hospital recruits approximately the same number of patients, i.e. 35 TKAs and 35 THAs during the study period.

7.9 Statistical software and significance level

All statistical analyses will be performed using standard statistical software (e.g. SPSS, R, or Stata). A two-sided p-value < 0.05 will be considered statistically significant. Effect sizes and 95% confidence intervals will be emphasized over sole reliance on p-values.

7.10 Interim analysis

An interim analysis will be performed after approximately 7 months (6 months plus 1 month follow up) to monitor the proportion of SDD, percentage of day-case surgery, readmissions within 30 days and the day-case related complications.

8. INSTITUTIONS AND RESPONSIBLE INVESTIGATORS

Study chair and principal investigator: Frank-David Øhrn.

Participating Sites:

- Volda Hospital

- Ålesund Hospital

- SNR (Molde/Kristiansund)

Support: research coordinator, statistician (MRHT), anesthesiology and orthopedic departments.

9. USER INVOLVEMENT

User participation is a legal and ethical requirement in Norwegian clinical research, anchored in the Health Research Act (Helseforskningsloven) and the guidelines from the Regional Committees for Medical and Health Research Ethics (REK).

User representatives help ensure that research questions, methodology, patient information, follow-up routines, and dissemination reflect real patient needs and priorities.

In the DART Study, user representatives participate in the project group and contribute to the development of protocols, patient communication materials, and advise on the feasibility of follow-up routines and digital data collection.

Such involvement strengthens the ethical foundation of the study, enhances recruitment potential, and increases the relevance and clinical impact of the study outcomes.

10. ETHICS

The study follows the Helsinki Declaration (26) and adheres to the STROBE (27) and ICMJE (28) recommendations. The study now holds an approval by REK (id number 982890) and Data Access Committee (DAC) and personal data officer of MRHT.

11. DATA SECURITY

All data in the prospective observational study will be registered in the already existing Quality registry of Møre and Romsdal Orthopaedic Research Group (MORE), and stored in eFORSK. Pseudo-anonymized before analysis. 10-year study period. The data will be stored 5 years after the study period has ended as obliged by Norwegian law. Data from the NAR and NPR will be stored on a safe research server with limited access especially designated for the purpose.

12. RISK AND SAFETY ASSESSMENT

THA and TKA are established procedures with well-described complication profiles such as infection, fractures, hip dislocation, nerve and/or vascular injury, and bleeding. The DART Study specifically evaluates the feasibility and safety of a structured *day-case* pathway. Safety monitoring therefore distinguishes between expected arthroplasty-related complications and complications plausibly related to same-day discharge and early outpatient management.

Serious adverse events (SAEs) are defined as any event resulting in death, being life-threatening, requiring hospitalisation or prolongation of hospitalisation, causing persistent or significant disability, requiring urgent intervention to prevent such outcomes, or otherwise judged medically significant.

All adverse events (AEs), SAEs, unplanned healthcare contacts, emergency department visits, and hospital readmissions occurring within 30 days following surgery will be recorded in dedicated case report forms (CRFs).

To ensure consistent and clinically meaningful classification of postoperative complications, all potential SAEs and readmissions will undergo structured clinical

adjudication using predefined criteria. Two investigators will independently assess each event. In cases of disagreement, consensus discussion will be undertaken and, if necessary, a third investigator will be consulted.

Events will be classified according to their presumed relationship to the day-case pathway:

1. Probably related to day-case management, including events such as uncontrolled pain after discharge, postoperative nausea or vomiting leading to healthcare readmission, dehydration, urinary retention or falls occurring shortly after discharge within 48 hours after surgery, inadequate mobilisation prior to discharge, , or inability to cope at home.

2. Possibly related to day-case management, including complications where early discharge may have contributed but where causality remains uncertain.

3. Probably unrelated to day-case management, including complications considered inherent to arthroplasty surgery regardless of length of stay, such as prosthetic joint infection, venous thromboembolism, prosthetic dislocation, periprosthetic fracture, myocardial infarction, or stroke.

In case of SAEs assessed as possibly or probably related to the day-case pathway, depending of the severity, an extraordinary safety meeting will be convened within the reference group to evaluate whether corrective actions are required, whether inclusion should be temporarily paused, or, in the most severe scenario, whether the study should be stopped. In that case, the steering committee will also be consulted.

All complications will be classified according to The Clavien-Dindo Classification and CCI will be calculated (17). All SAEs will subsequently be categorized as either expected arthroplasty-related SAEs or SAEs plausibly related to the day-case pathway.

Risks related to standard surgical procedures and regional anaesthetic techniques (FTB/GNB/PENG) will be monitored as part of routine perioperative care. Special attention with be given to patients receiving PENG blocks due to the risk of femoral nerve block and thus risk of falling. Grading of knee extension force from 1-5 sitting bedside will therefore be performed in all THA patients postoperatively. However, since these interventions constitute standard clinical treatment and are not unique to the day-case pathway itself, they are not considered study-specific risks unless the adverse outcome plausibly could have been prevented by continued postoperative hospital observation.

As the geography of Møre and Romsdal, with its fjords, mountains, and challenging weather conditions, may lead to prolonged and unpredictable travel times to acute care hospitals, special measures have been taken in the exclusion criteria of the DART Study.

13. REINTRODUCTION OF DAY-CASE ARTHRIOPLASTY SURGERY TO SNR KRISTIANSUND

The DART Study includes a predefined early implementation subproject at SNR Kristiansund. Depending of the time frame and project progress, decision can be taken either on the basis of the whole cohort or the interim analysis. Decision on this matter will be taken by the steering committee. The purpose of this subproject is to evaluate early safety, feasibility, and discharge success before considering transfer and routine implementation of day-case arthroplasty at SNR Kristiansund. The results from the interim analysis or the total cohort will form the basis for a structured and transparent decision regarding whether day-case THA, TKA and UKA can be safely transferred to clinical practice at SNR Kristiansund. Final recommendations on this matter will be made from the reference group, and this will be decisive for the final conclusion.

14. COST AND FINANCING PLAN

The DART Study is financed through institutional and regional research funding. MRHT provides funding for a study nurse/research coordinator in a 30% position throughout the study period. In addition, Central Norway RHA finances a full PhD fellowship integrated within the DART Study (3000 000 NOK). If required, additional applications for funding will be submitted to cover running study costs. The project leader currently holds a 40% position as a researcher in MRHT until March 2027. An extension of this position will be applied for upon expiry, and continuation is considered highly likely.

15. TIME SCHEDULE AND PUBLICATION PLAN

Year 1: Setup + inclusion start.

Year 2: Inclusion complete

Year 3: Follow-up, analysis, publications.

The scientific works of this project will be published in international peer-reviewed journals.

16. STUDY ORGANIZATION

Frank-David Øhrn, MD, PhD, researcher, study chair, pinsipal investigator and main PhD supervisor. Functions as the communication link between all groups and oversees coordination, protocol adherence, and study progress.

Kirsti Sevaldsen, MD, PhD, Associate Professor NTNU. Co-supervisor and member of the project group.

Tommy Frøseth Aae, MD, PhD. Co-supervisor and member of the project group.

PhD candidate Erik Ostnes, Consultant Orthopadic Surgeon, Volda Hospital, MRHT.

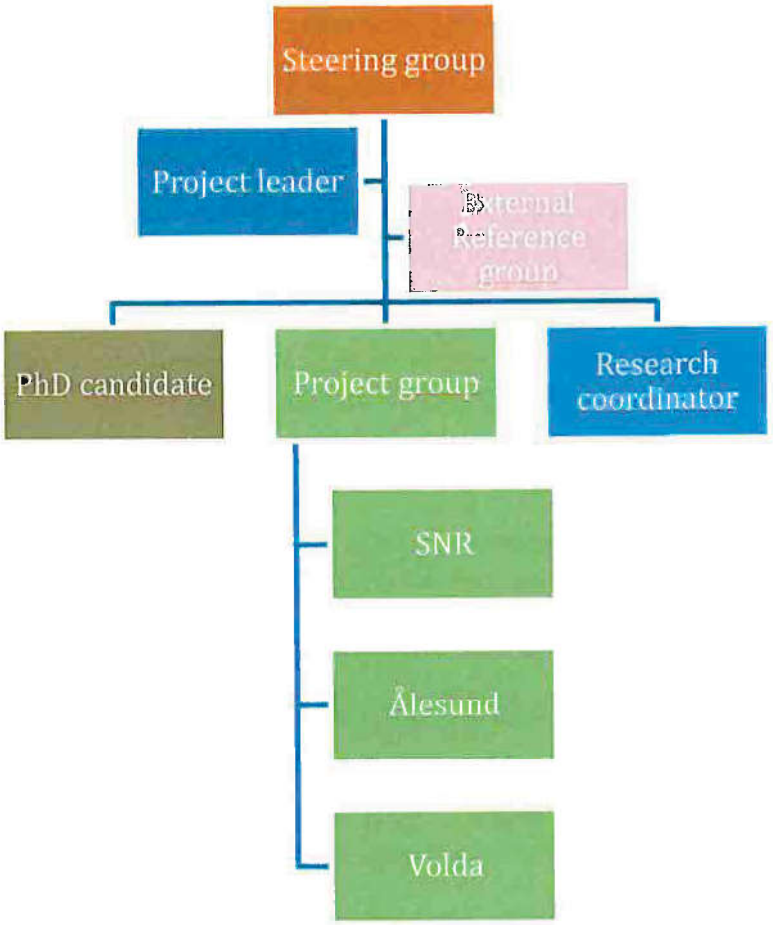


Figure 1 Organization map of the study

16.1 Participating Hospitals

Nordmøre and Romsdal Hospital (SNR), Ålesund Hospital and Volda Hospital

16.2 Steering group (Styringsgruppe)

Comprises leaders or representatives of leaders and well-known experts to ensure feasibility of the study across the Health Trust.

Erik Ganesh Iyer Søegaard, MD, PhD, Chief Medical Officer, MRHT

Britt Rakvåg Roald, Head of Clinic SNR, MRHT

Maren Pedersen, Head of Department of Surgery, Ålesund Hospital, MRHT

Geir Hallan, MD, PhD, Professor, University of Bergen

Gunnar Steve Dagslott, MD, Senior orthopaedic surgeon, Volda Hospital, MRHT

Ole Andreas Ørjansen Tomelthy, orthopaedic surgeon SNR and union representative for the Norwegian Medical Association (DNLF).

16.3 Project Group (Prosjektgruppe):

Comprises clinical and methodological experts such as anaesthesiologists, orthopaedical surgeons, nurses and representatives from logistics departments from all hospitals in MRHT who ensure alignment with best practice, external standards and feasibility of the study. Also included in the group is a biostatistician and user representatives.

16.4 Reference Group (Referansegruppe)

Provides overall strategic direction, approves milestones, supervises scientific quality.

Vigdis Schnell Husby, Nurse, PhD, Professor at NTNU

Stephan M. Röhrl, MD, PhD, Senior orthopaedical surgeon, Professor at the University of Oslo

Fredrik Isachsen, MD, Orthopaedical Surgeon, Head of Norsk Forening for Hofte og Knekirurgi (NFHKK), Nordlandet Hospital, Bodø, Helse Nord.

Are Hugo Pripp, PhD, Professor in biostatistics, University of Oslo and Oslo Metropolitan University.

Bjarte Askeland, MD, Anaesthesiologist, board member of Norsk Dagkirurgisk Forening (NORDAF)

Axel Sauter, MD, PhD, Anaesthesiologist, Oslo University Hospital.

The composition of the reference and project groups was approved by the steering committee of the study.

16.5 User representatives

Appointed by user committee (brukerutvalget) in MRHT:

Evy Anne Mortensen Svanemsli

Heidi Anita Johansen (alternative representative)

17 PROTOCL APPROVAL AND SIGNATURES

By signing below, the undersigned confirm that they have reviewed and approved the DART study protocol.

Project chair and principal investigator

Name: Frank-David Øhrn, MD, PhD

Signature:

Date: 2026-09-08

Chief medical officer of MRHT and chair of steering group of DART

Name: Erik Ganesh Iyer Søegaard, MD, PhD

Signature: E. Ganesh I. Søegaard

Date: 07.09.2026

18 Appendixes

18.1 Abbreviations

Abbreviation	Meaning
ASA	American society of anesthesiologists classification system
ATC	Anatomic Therapeutic Chemical Classification system
BMI	Body mass index
CCI	Comprehensive Complication Index
CFS	Clinical Frailty Scale
Central Norway RHA	Central Norway Regional Health Authority
CRF	Clinical report form
DAC	Data Access Committee of MRHT
DART	Day-case hip and knee Arthroplasty in Møre and Romsdal Trial
DBL	Database lock
EQ-5D	EuroQol 5 Demensions
FJS	The forgotten joint score
FL	First look
FPI	First patient in
FTB	Femoral triangle block
GNB	Genicular nerve block
HOOS	Hip disability and osteoarthritis outcome score
ICER	Incremental cost-effectiveness ratio
INGN	Inferior genicular nerve
IPACK	Infiltration between the popliteal artery and capsule of the knee
K&L	Kellgren & Lawrence radiologic classification
KOOS	Knee injury and osteoarthritis outcome score
LPI	Last patient in
LPO	Last patient out
NAR	Norwegian Arthroplasty Register

NRS	Numeric rating scale
NPR	Norwegian Patient Registry
NTNU	Norwegian university of science and technology
MRHT	Møre og Romsdal Hospital Trust (Helse Møre og Romsdal in norwegian)
PENG	Pericapsular nerve block
PONV	Postoperative nausea and vomiting
PROM	Patient reported outcome measure
QALY	Quality-adjusted life years
QoR15nor	Quality of recovery 15 Norwegian versjon
REK	Regional Committees for Medical and Health Research Ethics
RTA	Reflexive thematic analysis
SAE	Serious adverse effect
SDD	Same day discharge
SLGN	Superior lateral genicular nerve
SMGN	Superior medial genicular nerve
SNR	Nordmøre and Romsdal Hospital (Norwegian: Sykehuset Nordmøre og Romsdal)
TKA	Total knee arthroplasty
THA	Total hip arthroplasty
UKA	Unicondylar knee arthroplasty

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