CLINICAL STUDY PROTOCOL

HipSTHeR - a Register based Randomised Controlled Trial - Hip Screws or (Total) Hip Replacement for Undisplaced Femoral Neck Fractures in Elderly Patients.

Clinicaltrials identifier	NCT03966716
Version Number:	1.1
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Research Body:	Uppsala University
Principal investigator(s):	Olof Wolf, Sebastian Mukka

SYNOPSIS

Title: HipSTHeR - a Register based Randomised Controlled Trial - Hip Screws or (Total) Hip Replacement for Undisplaced Femoral Neck Fractures in Elderly Patients.

Rational for conducting the study: The aim of this study is to determine whether we can improve the treatment of elderly patients with an undisplaced femoral neck fracture (uFNF) by decreasing reoperation rates through replacing the hip instead of trying to preserve it. Patients ≥75 years with an uFNF will be included and randomised within the Swedish Fracture Register (SFR) platform to internal fixation (screws/pins) or arthroplasty (choice of hemi or total is at the surgeon's discretion).

Study design: Registry based randomised controlled clinical trial

Study population: Patients aged ≥75 years

Number of patients: 1440

Inclusion criteria:
• Written informed consent
• Age ≥75 years
• Acute (<72h) Garden 1 or 2 femoral neck fracture on conventional x-ray
• Eligible for internal fixation and hip arthroplasty
• Treatment at participating unit

Exclusion criteria:
• Pathological or stress fractures
• Peri-implant femoral neck fracture
• Previous inclusion of a contralateral Garden 1 or 2 femoral neck fracture

Primary outcome variables and examinations:
The primary outcome will be a composite variable that combines two variables (reoperations and mortality) into a single variable.

Study period: Sep 1st 2019-Dec 31st 2032

SIGNATURE PAGE

I confirm that I have read and understood this protocol and that I will work according to the protocol. By my signature, I agree to personally supervise the conduct of this study in my affiliation and to ensure its conduct in compliance with the protocol, informed consent, IRB/EC procedures, the Declaration of Helsinki, and local regulations governing the conduct of clinical studies.

Signature Principal Investigator	Date (yyyy-mm-dd)
Printed name of Principal Investigator	
Signature Head of Department	Date (yyyy-mm-dd)
Printed name of Head of Department	

Copy for study site; to remain with study protocol

SIGNATURE PAGE

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Signature Principal Investigator	Date (yyyy-mm-dd)
Printed name of Principal Investigator	
Signature Head of Department	Date (yyyy-mm-dd)
Printed name of Head of Department	

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TABLE OF CONTENTS

1. Introduction....9
1.1. Background....9
1.2. Rationale for conducting this study....9
1.3. Risk/Benefit evaluation....10
2. Study Objectives and Endpoints....10
2.1. Primary objective....10
2.2. Secondary objective(s)....10
3. Study Design and Procedures....11
3.1. Overall study design and flow chart....11
3.2. Rationale for study design....12
3.3. Study visits....12
3.4. Study assessments....13
4. Study Population....13
4.1. Inclusion criteria....13
4.2. Exclusion criteria....13
4.3. Subject enrolment and randomisation....13
4.4. Discontinuation and withdrawal of subjects....13
4.4.1. Premature termination of the study....13
4.5. Re-screening....14
5. Study Treatments....14
5.1. Identity of investigational implants....14
5.2. Blinding....14
5.3. Randomisation....14
5.4. Concomitant medication....14
6. Study Measurements and Variables....14
6.1. Primary variable....14
6.2. Secondary variable(s)....15
7. Statistics....16
7.1. Sample size calculation....16
7.2. Statistical analysis....16
8. Data Management....17
8.1. Recording of data....17
8.2. Data storage and management....17
9. Quality Control and Quality Assurance....17
9.1. Audits and inspections....17
10. Ethics....17
10.1. Ethics committee....18
10.2. Informed consent....18
10.3. Subject data protection....18
10.4. Insurances....18
11. Protocol Deviations and Amendments....18
12. Report and publications....19
13. Study Timetable....19
13.1. Study period....19

13.2. Definition of “End of study”.....19
14. Amendments to the study protocol.....19
14.1. PROM follow up.....19
15. List of References.....21
Appendix.....23
1. ICD codes for primary outcome. 23

LIST OF ABBREVIATIONS

Abbreviation	Explanation
rRCT	Register-based Randomised Controlled Trial
FNF	Femoral Neck Fracture
uFNF	Undisplaced Femoral Neck Fracture
dFNF	Displaced Femoral Neck Fracture
IF	Internal Fixation
NPR	National Patient Register
SHAR	Swedish Hip Arthroplasty Register

1. INTRODUCTION

1.1. Background

Hip fractures are a major cause of injury, morbidity and death in the elderly. Undisplaced FNF (uFNF) are classified according to the Garden classification system on the anteroposterior X-ray [1, 2]. The routine surgical procedure for uFNFs, regardless of the patient's age, is internal fixation (IF) with 2-3 screws or pins. The use of hip arthroplasty for undisplaced FNF is widely used by large parts of the orthopaedic communities, despite the paucity of high quality studies comparing IF and hip arthroplasty [3]. Advanced age has been described as a risk factor for healing complications in uFNFs [4,5]. In elderly patients' reoperation rates ranging between 8 and 21% have been reported in the literature [1, 6, 7]. In elderly patients displaced FNFs are treated with hip arthroplasty, which produces better and more predictable results compared with IF [7]. The reoperation rate for hemiarthroplasties for displaced FNFs is lower than for undisplaced fractures that are operated with IF [7-9]. A randomised controlled trial (RCT) comparing modern hemiarthroplasty with screw fixation for uFNFs found no significant difference in hip function but hemiarthroplasty led to improved mobility and fewer major reoperations [9].
In the Swedish Fracture Register (SFR) all fracture types in adults and all long-bone fractures in children are registered [10]. The SFR is a unique national quality register as it contains information on fractures, regardless of treatment (surgical or non-surgical). Seventy-five per cent of the hospitals in Sweden that manage fractures on a regular basis participate in the SFR.
A question often arises as to whether the results from an RCT can be extrapolated from the study environment to a general health care setting [11, 12]. Active participation of patients and recruitment of large sample sizes in an RCT are not easily achieved and refusal to participate and loss to follow-up (a form of selection bias) are prevalent problems. Conducting register-based RCTs (rRCTs), which include a randomisation module in a large, all-inclusive clinical register with unselected consecutive enrolment, can combine some of the most important features of a prospective randomised trial with the inclusiveness and efficiency of a large-scale clinical register. The consecutive enrolment in combination with patient identification and automated linked register-based follow-up allows for a cost-effective model with analysis of those who are lost to follow-up [13].
There are limited data comparing IF and hip arthroplasty for uFNF fractures and trials have been called for to optimise the surgical treatment [1, 14].

1.2. Rationale for conducting this study

The aim of this study is to determine whether we can improve the treatment of elderly patients with an uFNF by decreasing reoperation rates through replacing the hip instead of trying to preserve it. Patients ≥75 years with an uFNF will be included and randomised within the Swedish Fracture Register (SFR) platform to IF (screws/pins) or arthroplasty (choice of hemi or total is at the surgeon's discretion). The primary outcome will be a composite variable that combines two variables (reoperations and mortality) into a single variable.

1.3. Risk/Benefit evaluation

The standard treatment of undisplaced FNFs in Scandinavia is closed reduction and IF with 2-3 screws or pins. Other countries have either been more conservative, practicing non-operative treatment up until recent years [15], or already changing to primary arthroplasty treatment even if evidence is lacking (as described in this protocol). There is a true equipoise in this matter. The longer, and maybe more strenuous, procedure of primary arthroplasty is weighted against internal fixation, with a higher crude number of fracture failures and reoperations. If arthroplasty carries a higher risk of peri- and postoperative mortality, it will besides increased suffering for the patients also mask potential reoperations. But when studying displaced FNFs (dFNF), the Norwegian Hip Fracture Register show that the 1-year mortality was not affected by the choice of treatment modality (IF or arthroplasty) [9]. None of the RCTs on dFNFs proceeding the paradigm shift in Scandinavia, when we went from IF to arthroplasty for dFNFs, showed any differences in mortality. Actually, a recent RCT comparing hemiarthroplasty and IF in patients with uFNF reported a higher mortality rate after IF [9]. So, extrapolating from existing literature, we do not see an impendent risk in this aspect.
The postoperative regime after arthroplasty is more straightforward, compared to IF where some surgeon recommends restricted weight bearing. In addition, up to 40% of patients experience hip pain 2 to 3 years following IF. Not denying that arthroplasty (hemi or total) will be a somewhat more invasive surgical procedure, we think advantage of full weight bearing mobilization with a probable lower complication rate will justify this.
Despite the higher initial cost for arthroplasty, the expected lower rates of reoperations are expected to health economic savings for both the society and the individual hospital.

2. STUDY OBJECTIVES AND ENDPOINTS

2.1. Primary objective

1) The primary objective of this study is to determine whether we can improve the treatment of elderly patients with an uFNF by decreasing reoperation rates by using hip arthroplasty instead of the standard treatment with osteosynthesis.

Our primary outcome will be a composite variable consisting of the two variables reoperation rate and mortality. This composite variable will therefore be a measure or variation in both reoperation and mortality rates in a control and intervention group. This is an important point because the literature and register data suggest that reoperations are reduced in the arthroplasty group but primary arthroplasty could be associated with a higher peri-operative mortality. The two indicators of this composite variable will be separately investigated within our secondary outcome measures.

2.2. Secondary objective(s)

The secondary objective(s) of this study are to evaluate:

1) If elderly patients tolerate the more demanding surgical procedure of arthroplasty and the potential risks of 3-month and 1-year mortality.
2) If the patients in the arthroplasty group are at higher risk of peri- and post-operative complications than those with IF.

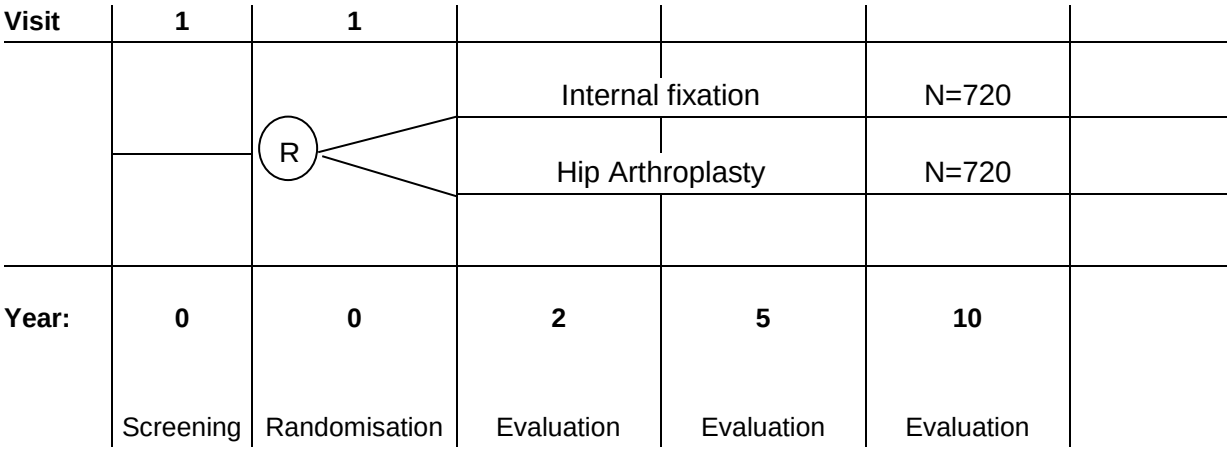
3) Differences in the occurrence of adverse events, including pulmonary embolism, infection, dislocation, myocardial infarction and stroke.
4) Occurrence of any selection bias in the screening process. We intend to assess external validity through analyzing the outcome of patients not included in the study. Do participants differ from eligible nonparticipants.

3. STUDY DESIGN AND PROCEDURES

3.1. Overall study design and flow chart

The study is designed as a multicenter registry-based RCT (rRCT) and the outcome variables will be drawn from other registers after cross-checking with national registers. The study will not be blinded. The study is expected to be conducted between 2019 and 2032 (Inclusion period 2019-2022). A schematic diagram of trial design, procedures and stage below.

Figure 1 ***Study design: Register based randomised controlled trial***



3.2. Rationale for study design

The rRCT study design enables us to perform a national multicenter randomised controlled trial without any additional follow-up. In this elderly population, the main advantage is the possibility to recruit a large sample size without burden the patients with additional follow-up visits. The Swedish personal identity number (PIN) allows the investigator to cross-check registers on an individual level. Data on fracture classification, age, sex, type of trauma, time of diagnosis with X-ray, time of surgical treatment will be collected in the SFR and the randomisation will be done within the SFR registry-platform after informed consent has been obtained from the patient. Further variables will be registered by cross-checking with the Swedish Hip Arthroplasty Register with data on type of arthroplasty used (hemi or total hip), fixation method, manufacturer and type of components and any revision surgery performed. Data on reoperations are registered in the National Patient Register (NPR). Mortality is automatically cross-checked with the Swedish Cause of Death Register and available in the SFR.

3.3. Study visits

There will be no formal clinical follow-up visits in addition to the local clinical routines. Data on reoperations and mortality are registered in the National Patient Register (NPR).

Table 1 ***Study activities***

Day:	Visit 1 Screening and randomisation 0	Follow-up 2y	Follow-up 5y	Follow-up End of Trial 10y
Informed consent	X			
Demography	X			

Inclusion/exclusion criteria	X			
Randomisation	X			
Outcome		X	X	X

3.4. Study assessments

4. STUDY POPULATION

4.1. Inclusion criteria

For inclusion in the study, subjects must fulfil the following criteria:

1. Written informed consent
2. Age ≥75 years
3. An acute (<72h) Garden 1 or 2 femoral neck fracture diagnosed with conventional X-ray
4. Eligible for internal fixation and hip arthroplasty
5. Treated at participating unit

4.2. Exclusion criteria

Subjects must not enter the study if any of the following criteria are fulfilled:

1. Pathological or stress fracture
2. Peri-implant femoral neck fracture
3. Previous inclusion of a contralateral Garden 1 or 2 femoral neck fracture

4.3. Subject enrolment and randomisation

Subject eligibility will be established before treatment randomisation. Subjects will be randomised strictly sequentially, as subjects are eligible for randomisation. If a subject discontinues from the study, the subject number will not be reused, and the subject will not be allowed to re-enter the study.

4.4. Discontinuation and withdrawal of subjects

Subjects are free to discontinue their participation in the study at any time without prejudice to further treatment. Patients will be withdrawn from study if the patient withdraws consent. Already collected study data for these patients will be kept in the study database, however new data, including data from registries will not be added. Patients prematurely withdrawn from the study will not be replaced.

4.4.1. Premature termination of the study

The study group may decide to stop the trial or part of the trial at any time. Furthermore, the investigator should promptly inform the Ethics Committee and provide a detailed written explanation.

4.5. Re-screening

Re-screening is allowed before surgical treatment has been performed.

5. STUDY TREATMENTS

5.1. Identity of investigational implants

The choice of supplier, brand and type of implants are based on the preference of each participating center.

Internal fixation
Internal fixation is carried out with the patient on a fracture table. The fracture is reduced if possible using a closed reduction with the aid of an image intensifier and fixed with two or three cannulated screws or pins. In the anteroposterior projection, the distal screw is aimed to be at the level of the lesser trochanter and to rest on the medial inferior cortex of femoral neck. The proximal screw is positioned parallel at least one cm from the distal screw.

Hip arthroplasty
Patients included in the RCT will be treated with either a total hip arthroplasty or a hemiarthroplasty. The surgical approach used is at the preference of the treating surgeon, the most commonly used surgical approaches are the direct lateral and the posterior. The femoral stem is either a cemented or an uncemented type. For hemiarthroplasty either a unipolar or bipolar head are used. For total hip arthroplasty, a modular femoral head is used together with a cemented or uncemented acetabular cup of dual mobility or a conventional type.

5.2. Blinding

There will be no blinding. The surgical procedures do not allow for any blinding of the patient due to the differences in length of the surgical incision.

5.3. Randomisation

This study is designed as a register-based RCT based on the platform of the Swedish Fracture Register. The subjects are randomised in a 1:1 ratio to receive internal fixation (controls) or hip arthroplasty, using permuted block randomization stratified for sex. Randomisation will be performed through the web-based platform of the Swedish Fracture Register.

5.4. Concomitant medication

Patient will receive their ordinary medications and the standard pre- and postoperative treatment at each participating center.

6. STUDY MEASUREMENTS AND VARIABLES

6.1. Primary variable

The primary outcome of this rRCT will be a composite variable that includes reoperation rate and mortality. Arthroplasty is a more elaborate surgical procedure that might affect peri- and post-operative short-term mortality, related to longer operating times, higher blood loss, and the

occurrence of bone cement implantation syndrome. Therefore, we construct a composite variable as the primary outcome SFR.

Primary endpoints will be evaluated for the time points 2, 5 and 10 years after the patient has been randomised. Primary and secondary endpoints are listed in table 2. Information will be collected retrospectively from registries.

Primary Endpoints from NPR, SFR, SHPR

- Time to reoperation due to periprosthetic infection
- Time to reoperation due to periprosthetic fracture
- Time to reoperation due to prosthetic dislocation
- Time to reoperation due to prosthetic loosening
- Time to reoperation due to acetabular erosion
- Time to reoperation due to non-union
- Time to reoperation due to mechanical failure of internal fixation
- Time to reoperation due to post-traumatic osteoarthritis
- Time to reoperation due to deep infection
- Time to death

6.2. Secondary variable(s)

The secondary objective(s) of this study is to evaluate if elderly patients tolerate the more demanding surgical procedure of arthroplasty and the potential risks of 3-month and 1-year mortality. Whether the patients in the intervention group are at higher risk of peri- and post-operative complications than the controls.

Differences in patient reported outcome.

Differences in the occurrence of adverse events, including pulmonary embolism, infection, dislocation, myocardial infarction and stroke.

Occurrence of any selection bias in the screening process. We intend to assess external validity through analyzing the outcome of patients not included in the study. Do participants differ from eligible nonparticipants.

Secondary Endpoints extracted from NPR, SFR, SHPR

- Time to reoperation due to any reason presented in table 2.
- Time to death
- Patient reported outcome measured by The Short Musculoskeletal Functional Assessment [16] at 1 year reported to SFR.
- Time to occurrence of adverse events.
- The external validity of the trial will be evaluated by comparing mortality, reoperations and patient-reported outcome measures between those who were included in an rRCT compared to those who fulfill the inclusion criteria for the rRCT trial but declined participation. Data will be extracted from NPR, SFR and SHAR.

7. STATISTICS

7.1. Sample size calculation

The reoperation rate for hemiarthroplasty because of FNF is 5% according to reports from the Swedish Hip Arthroplasty Register (SHAR). Because we know that the variable “reoperations” does not have 100% completeness in the SHAR inasmuch as some procedures (e.g., debridement and irrigation) are not reliably registered, we assume that the actual reoperation rate is closer to 7.5%. The reported reoperation rates for uFNFs vary, but we estimate that the rate is about 12.5% at 1 year after IF with screws/pins in elderly patients with uFNF.

In our primary outcome composite variable, we expect a 15% 1-year mortality within the study cohort.

We assume that death or reoperation would occur within 1 year in 27.5% of patients in the control group (IF), and aim to detect a decrease to 22.5% in the intervention group (arthroplasty). We plan to include patients during 3 years, with a total study duration including 10-year follow-up of 13 years. Patients will be censored at the end of study or at most 2 years, hence about 2/3 will have 2 years’ follow-up and the remaining patients between 1 and 2 years. Simulations under an assumption of constant hazard indicate that a total of 1440 patients enrolled during 3 years, yielding about 586 events, would give 80% power to detect such a difference. The analyses were performed using R v. 3.3.1 and the survival package v. 2.39.4.

7.2. Statistical analysis

Time to first event will be presented as Kaplan-Meier plots. The primary composite and the individual components will be analyzed for time to first event using Cox regression adjusted for sex and for age as a linear covariate, and presented as hazard ratios with 95% confidence intervals and p-value. Events after more than 2 years will be censored. Due to the registry follow-up, we assume that follow-up will be complete for mortality and reoperations. In the rare case that a patient is known to have incomplete follow-up, the patient will be considered censored at last known follow-up. For the reoperation endpoint, death will be handled as censoring.

The number of patients with perioperative event, event within 1 year, and event within 2 years will be summarized in tables. Patients lost to follow-up will be included in the denominator, and the 2-year frequencies will only include patients randomised at least 2 years before data collection.

Supplementary sensitivity analyses will include analyses censored at 1 year, and analyses of number of patients with events, perioperatively, and within 1 and 2 years. These analyses will primarily use logistic regression, and as a supplement risk differences with Wald confidence interval.
Analyzes will be performed both as intention-to-treat and per protocol.
Secondary outcomes will be presented in the same way as the primary composite and its components. Patient reported outcome (SMFA) will be analyzed using students t-test.
Statistical expertise will perform the statistical analysis.

8. DATA MANAGEMENT

8.1. Recording of data

All study data will be transferred from SFR into the study database, with the exception of the screening question answers that will be entered into the study database from the SFR interface. Outcome data will be collected retrospectively from registries.
The written informed consent will be stored at the study site. The investigator ensure that all source documents are accessible for monitoring.

8.2. Data storage and management

All data should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification. All source data including informed consent at each participating study center, a copy of the completed study database, original protocol with amendments and the final report will be stored at the orthopaedic department at Uppsala University Hospital for a minimum period of 25 years after termination of the trial, according to the EU regulation 536/2014 (or ten years after termination of the trial, in accordance with Swedish law (Chapter 10, in LVFS 2011:19)).

At the conclusion of the study, the occurrence of any protocol deviations will be determined. After these actions have been completed and the database has been declared to be complete and accurate, it will be locked and available for data analysis.

9. QUALITY CONTROL AND QUALITY ASSURANCE

The coordinator will have regular contacts with the clinic to verify informed consents of participating subjects, to confirm that facilities remain acceptable, that the investigational team is adhering to the protocol, to verify inclusion/exclusion criteria, study main endpoints. The investigator should ensure that all persons assisting with the trial are adequately informed and trained about the protocol, and their trial related duties and factions.

9.1. Audits and inspections

Authorized representatives of the study group, or an Ethics Committee may perform audits or inspection at the center. The investigator must ensure that all study documents are accessible for auditing and inspection. The purpose of an audit or inspection is to systematically and independently examine all study-related activities and documents, to determine whether these activities were conducted, and data were recorded, analyzed and accurately reported according to the protocol, and any applicable regulatory requirements.

10. ETHICS

The study will be performed in accordance with the protocol, with the latest version of the Declaration of Helsinki, and applicable regulatory requirements. The regional ethical committee at Uppsala University has approved the study (dnr 2019-00140).

10.1. Ethics committee

The final study protocol, including the final version of the Informed Consent Form and other information given to subjects e.g. advertisements, must be approved or given a favorable opinion in writing by an Ethics Committee (EC) as appropriate. The Principal Investigator is responsible for informing the EC of any amendment to the protocol, in accordance with local requirements.

10.2. Informed consent

The principal Investigator at each center will ensure that the subject is given written information about the nature, purpose and possible risks and benefits of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.

The subject's signed and dated informed consent must be obtained before conducting any procedure specifically for the study. The monitor(s) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject' or the subject's legally acceptable representative is authorizing such access.

The original, signed Informed Consent Form (ICF) must be stored at the study site. A copy of the signed ICF must be given to the subject.

If a protocol amendment requires a change to the ICF, the EC must approve modifications that lead to a revised ICF before the revised form is used.

10.3. Subject data protection

The Informed Consent Form will incorporate wording that complies with relevant data protection and privacy legislation. Pursuant to this wording, subjects will be informed about the collection and by those persons who need that information for the purposes of the study.
The Informed Consent Form will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation. All data computer processed by the study group will be identified by Study Code.
The Informed Consent Form will also explain that for data verification purposes, authorized representatives of the study group, a regulatory authority or an Ethics Committee may require direct access to parts of the hospital or practice records relevant to the study, including subjects' medical history.

10.4. Insurances

The study subjects are covered by the Swedish Patient Injury Act.

11. PROTOCOL DEVIATIONS AND AMENDMENTS

Modifications to the signed protocol are only possible through approved protocol amendments and with the agreement of all responsible persons. Details of non-substantial amendments are to be clearly noted in the amended protocol.

A change that concerns; a new trial site, new principal investigator and or a new informed consent form should only be submitted to the concerned Ethics Committee.
In case of a substantial protocol amendment (e.g. change of; main purpose of the trial, primary/secondary variable, measurement of primary variable), the concerned Ethics Committee must be informed and should be asked for its opinion/approval prior implementation of amended protocol, as to whether a full re-evaluation of the ethical aspects of the study is necessary by the committee. This should be fully documented.

The Investigator must not implement any deviation from, or change to the protocol, without discussion with, and agreement by the study group and prior review and documented approval/favorable opinion of the amendment from the relevant ethics committee, except where it is necessary to eliminate an immediate hazard to study subjects, or where the change(s) involves only logistical or administrative aspects of the study (e.g. change of telephone numbers).

12. REPORT AND PUBLICATIONS

After completion of the study, the results will be analyzed and a clinical study report will be prepared. Within one year after the end of the study, the study group will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited Ethics Committee. In addition, upon study completion and finalization of the study report the results of this trial will be either submitted for publication and/or posted in a publicly accessible database of clinical trial results.

13. STUDY TIMETABLE

13.1. Study period

Estimated subject enrollment start: 2019-09-15
Subject enrollment stop: 2022-12-31
Subject last follow-up: 2029-12-31

13.2. Definition of “End of study”

The study group will notify the concerned Ethics Committee of the end of the study within a period of 90 days. *End of study is defined as last visit of the last subject.*

14. AMENDMENTS TO THE STUDY PROTOCOL

14.1. PROM follow up

Date of amendment: 2020-12-15

If the patient included in this RCT has not responded to the invitation from the Swedish Fracture registry to answer PROM (patient reported outcome measurement) the studygroup will send out an extra invitation by letter for the one year follow up.

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Appendix
1. ICD codes for primary outcome.

Diagnos vid revision och reoperation

ICD-10 kod I ICD-10 kod II	ICD-10 kod III Beskrivning
T81.4 Y83.1	Sårinfektion, ytlig
T84.5F Y83.1	Protesinfektion
T84.0F Y83.1	Protesluxation
T84.0F M24.4F	Y83.1 Recidiverande protesluxation
M61.4 Y83.1	Ektopisk bennybildning efter op
M89.5 Y83.1	Osteolys, protesnära
T84.0f Y79.2	Implantathaveri/brott/slitage
T84.0F Y83.1	Proteslossning
M96.6F Skadekod (V, W eller Y-kod) Protesnära fraktur	
M84.0F	Felläkning av fraktur
M84.1F	Utebliven läkning/pseudoartros
M84.2F	Fördröjd frakturläkning
M87.2F	Ostenekros efter tidigare skada
T84.1	Mek kompl instr för inre fix av extremitetsben
T84.3F	Mek kompl av andra instrument, implantat
T84.6F	Infektion efter osteosyntes
T91.2	Sena besvär av annan frakt på br-korgen o bäckenet
T93.1	Collumfraktur, sena besvär efter
T81.0 Y83.1 Blödning/hematom M84.1F T93.1 Y86.9 Utebliven läkning höftfraktur M79.6F Ospecifik smärta T93.4 Nervskada	
T93.8 Kärlskada	
T93.5 Muskel-/senskada M16.1 Primär artros (halvprotes) T84.0F M16.7 Y83.1 Acetabulumerosion (halvprotes)	
T81.3 Sårruptur (ej infektion)	
T84.5F Y83.1 ALVAL/Pseudotumör	
T84.8F Y65.8 Fel i implantatpositionering/implantatstorlek	

Åtgärdskoder vid reoperation

Primära protesoperationer	
NFB09	Primär halvprotes cementfri
NFB19	Primär halvprotes med cement
NFB29	Primär totalprotes cementfri
NFB39	Primär totalprotes hybridteknik
NFB49	Primär totalprotes med cement
NFB62	Primär total ytersättningsprotes
NFB99	Annan primär ledprotesop
Revisioner (sekundära protesoperationer)	
Utan cement	
NFC09	Sek halvprotes cementfri
NFC20	Sek totalprotes cementfri, totalrev
NFC21	Sek totalprotes cementfri, cuprev
NFC22	Sek totalprotes cementfri, stamrev
NFC23	Sek totalprotes cementfri, annan del
NFC29	Sek totalprotes cementfri, annan rev
Hybrid	
NFC30	Sek totalprotes hybrid, totalrev
NFC31	Sek totalprotes hybrid, cuprev
NFC32	Sek totalprotes hybrid, stamrev
NFC33	Sek totalprotes hybrid, annan del
NFC39	Sek totalprotes hybrid, annan rev
Med cement	
NFC19	Sek halvprotes med cement
NFC40	Sek totalprotes med cement totalrev
NFC41	Sek totalprotes med cement cuprev
NFC42	Sek totalprotes med cement stamrev
NFC43	Sek totalprotes med cement, annan del
NFC49	Sek totalprotes med cement, annan rev
Övriga sekundära ledprotesoperationer	
NFC99	Annan sek ledprotesoperation (byte liner och/eller caput) samt vid konvertering halvprotes till totalprotes
Kompletterande åtgärder	
NFN09	Autotransplantation av ben till femur
NFN19	Homotransplantation av ben till femur
NEN09	Autotransplantation av ben till bäcken
NEN19	Homotransplantation av ben till bäcken
NFC59	Sek implantation av interpositionsprotes (spacer)
Reoperationer	
NFU09	Extraktion av halvprotes

NFU19	Extraktion av totalprotes
NFU39	Extrakt av ext fixationsmtrl
NFU49	Extrakt av int fixationsmtrl
NFU89	Extraktion implantat infbeh
NFA12	Öppen exploration av höftled
NFH22	Öppen reposition av luxerad protes
NFL49	Sutur/reinsertion av sena/muskelfäste
NFS09	Incision/debridering vid (ytlig) mjukdelsinfektion i höft eller lår
NFS19	Incision/debridering vid septisk artrit
NFS49	Implantation av läkemedel vid septisk artrit
NFT12	Öppen mobilisering av led
NFL19	Sutur/rekonstruktion av muskel
NFU49	Extraktion av internt fixationsmaterial
NFS99	Annan op vid infektion
NFG09	Excisionsartroplastik (Girdlestone)
NFQ09	Exartikulation i höftled
Kod vid tidig reoperation	
NFW49	Sutur av sårruptur
NFW59	Reop för ytlig sårinfektion
NFW69	Reop för djup infektion
NFW79	Reop för sårblödn/hematom
NFW89	Reop för djup blödning
NFW99	Annan reoperation
Frakturåtgärder	
NFJ59	Osteosyntes med märgspik
NFJ69	Osteosyntes med platta
NFJ99	Annan frakturåtgärd
Slutna operationer	
NFH20	Sluten reposition av luxerad protes