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Scandinavian Olecranon Research in the Elderly (SCORE): Protocol for a non-inferiority, randomised, controlled, multicentre trial comparing operative and conservative treatment of olecranon fractures in the elderly.

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Abstract

Introduction

The incidence of olecranon fractures is growing in the elderly population. The traditional operative approach is giving way among the elderly to conservative treatment, which seems to provide a comparable functional outcome with a lower complication burden. However, there is still a lack of reliable evidence to support this shift.

The objective of this trial is to investigate whether conservative treatment of displaced olecranon fractures in patients aged 75 or older yields comparable results to those of operative treatment in terms of pain and daily function.

Methods and analysis

Scandinavian Olecranon Research in the Elderly (SCORE) is a randomised, controlled, multi-centre, non-inferiority-trial. Eligible patients will be randomised to either conservative or operative treatment. The sample size will be 68 patients and allocation done at a 1:1 ratio (34 patients per group). The randomisation is stratified according to the participating hospital and patient's sex. Both groups will receive the same post-operative physiotherapy and pain management. The primary outcome is Disabilities of the Arm, Shoulder and Hand (DASH) at one-year follow-up. Secondary outcomes are pain and satisfaction measured on visual analogue scales, Patient Reported Elbow Evaluation (PREE), range of motion of the elbow and extension strength of the elbow compared to the unaffected arm. Radiographs will be taken at each follow-up. Primary analysis of the results will be conducted on an intention-to-treat basis.

Ethics and dissemination

The study protocol for this clinical trial has been approved by the Ethics Committee of the Hospital District of Southwest Finland and will be submitted for approval to the Regional Ethics Committees in Linköping, Sweden and Copenhagen, Denmark. Every recruiting centre will apply local research approvals. The results of this study will be submitted for publication in peer-reviewed journals.

Trial registration number (ClinicalTrials.gov)

NCT04401462.

Key words: Intra-Articular Fractures; Ulna Fractures; Fractures, Closed; Osteoporotic Fractures; Elbow Joint; Ulna; Fracture Fixation, Internal; Open Fracture Reduction; Conservative Treatment

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Strengths and limitations of this study

- Our study will eventually demonstrate whether conservative treatment can be applied as a first choice to olecranon fractures in the elderly population.
- The multicentre setup with three participating countries increases the generalisability and external validity of this trial.
- The results of this trial are limited to cooperative patients aged 75 years or older, which will limit the external validity of the trial, as a significant proportion of patients in this age-group are non-cooperative due to dementia or other comorbidities.

INTRODUCTION

Background and rationale

Olecranon fractures account for roughly 1% of all upper extremity fractures [1]. Current epidemiological data suggest that the incidence of olecranon fractures is increasing in the elderly population after the seventh decade [1,2] (Motisi). Displaced olecranon fractures have traditionally been treated operatively with osteosynthesis [3]. The most frequent operative methods for fixating a displaced olecranon fracture are tension band wiring (TBW) and plate fixation (PF). According to previous observational studies, both methods achieve adequate union and function but are also associated with a high rate of re-operations due to operative complications and removal of symptomatic fixation materials after fracture union [4–7]. Reported re-operation rates vary, reaching up to 16 – 50 % for TBW and 15 – 33 % for PF [4,8–11].

Non-operative, or conservative, treatment has been suggested as a treatment option for elderly patients in whom the function of the injured elbow does not necessarily significantly limit their daily activities. Based on data from a small retrospective series, it seems that conservative treatment could provide a similar functional outcome, with a lower complication burden, for this population [12–14]. A recent study of a US population reported a 0.66 % annual increase in non-operative management of olecranon fractures in patients aged over 75 years [15].

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To our knowledge, there is only one published and one ongoing randomised study comparing operative and conservative treatment in elderly patients [10,16]. The published trial was terminated prematurely because of an unacceptably high complication rate in the operative group [10]. As operative treatment of an isolated displaced olecranon fracture is still common in the elderly, further research is needed on the role of primary conservative treatment in this patient group.

Objectives and study hypothesis

The aim of this trial is to study the difference between operative treatment, either with TBW or PF, and conservative treatment of traumatic, displaced (Mayo 2 [17,18]) olecranon fractures in the elderly population in a non-inferiority study setting. Our null hypothesis is that conservative treatment does not yield inferior outcomes to operative treatment.

Trial design

SCORE is an ongoing, non-inferiority, randomised, controlled, multicentre trial, with two parallel treatment groups (1:1).

METHODS

Study setting

The study protocol is designed in accordance with the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials) [19]. The trial will be conducted as a multicentre study. The following hospitals participated in designing the study protocol: five university hospitals (Helsinki University Central Hospital, Turku University Central Hospital, Tampere University Hospital, Oulu University Hospital, Kuopio University Hospital) and two regional hospitals (Central-Finland Central Hospital in Jyväskylä and Satakunta Central Hospital in Pori) in Finland, and University Hospitals in Linköping, Sweden and Copenhagen,

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Denmark. All three countries have a country manager responsible for organising participation locally. Patients will be recruited at the trauma centres of the participating hospitals.

Eligibility criteria

A member of the study group will assess the eligibility of patients with displaced olecranon fractures referred to the recruiting centres. Diagnosis will be verified using conventional radiographs (standard AP and lateral radiographs). Inclusion and exclusion criteria are listed in box 1. All eligible patients will be asked to participate in the trial and written informed consent obtained. The two treatment modalities will be openly and carefully explained to the patients at recruitment. All screened patients meeting the inclusion criteria will be recorded.

Interventions

Operative group

Patients in the operative group will be prepared for surgery according to the standard of care (plexus and/or general anaesthesia based on anaesthesiologist's evaluation, antibiotic prophylaxis), and surgery will take place within two weeks of the injury. Patients will undergo surgical fixation by the preferred technique of the treating, attending or fellow surgeon (TBW or PF according to AO instructions [20]) in a manner consistent with the usual protocol of the participating institution. Post-operative protocol will include immobilisation either with a sling or a long-arm plaster splint for two weeks followed, by progressive range of motion as tolerated.

Conservative group

Conservative treatment will consist of a sling and immediate progressive range of motion as tolerated. A long-arm plaster splint may be applied for two weeks if needed for pain control and after splint removal active movements will be started as tolerated.

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In both treatment groups the patients will be referred to physiotherapy at two weeks. All patients will be prescribed painkillers, according to local care standards, as needed. Patients will be referred to a ward at their local health centre for rehabilitation if they are unable to manage at home.

Outcomes

Baseline data

After enrolment the following baseline demographics will be recorded: date of birth, sex, date of injury, mechanism of injury, dominant hand, affected side, smoking, possible diabetes or inflammatory arthritis, and whether the patient lives in a facility. In addition, a clinical frailty scale [21] and Disabilities of the Arm, Shoulder and Hand (DASH) [22,23] questionnaire will be completed at baseline for comparison of the treatment groups. Patients will be asked to answer the DASH questionnaire describing their elbow function within two weeks before the injury.

Primary outcome

Disabilities of the Arm, Shoulder and Hand (DASH)

The primary outcome compares the DASH [22,23] score at one year between treatment groups. DASH is a validated patient-reported outcome measure assessing upper-extremity related deficits and symptoms in daily life. The instrument consists of 30 items, of which at least 27 must be answered for a score to be calculated. The additional four optional items related to work, sports and music (four items each), are discarded in our study. The score ranges from 0 (no disability) to 100 (extreme disability). DASH is available and validated in several languages including Finnish [24], Swedish [25], and Danish [26]. The MCID (minimal clinically important difference) for this questionnaire is 10 points [23,27].

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Secondary outcomes

Secondary outcomes are both subjective and objective measurements. A full list of secondary outcomes is shown in box 2. Radiographs of the affected arm will also be taken at each control visit and analysed according to the detailed evaluation list shown in box 3.

Visual analogue scale; pain and satisfaction

Pain will be assessed on a 0 to 100mm visual analogue scale (VAS), from 0 on the left 'no pain' to 100 on the right 'worst possible pain'. VAS is the most frequently used assessment instrument for pain in clinical settings and is structurally simple to use [28]. Satisfaction with treatment and elbow function will be assessed similarly on a visual analogue scale, from 0 on the left 'best possible situation' to 100 on the right 'worst possible situation'.

Patient Rated Elbow Evaluation (PREE)

PREE is an elbow joint specific measure of pain and disability and is validated with psychometric methods [29]. The instrument consists of two subsections: pain with five items and function with fifteen. The subsections are computed to weigh pain and disability equally and both are scaled from 0 'best score' to 50 'worst score'. Total score is the sum of subscales. A higher score indicates more pain and functional disability.

Participant timeline

All patients will have a follow-up appointment at two weeks and three and 12 months. The detailed schedule for assessments is outlined in table 1 and the flow chart of the trial is shown in figure 1.

Sample size

The power calculations are based on assumed behaviour of the DASH questionnaire. The non-inferiority margin was determined to be MCID for this questionnaire, which is 10 points [23,27]. The standard deviation of DASH is assumed to be 15 [30]. Estimated sufficient sample size is based on simple two-sample t-test with

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one-sided alternative hypothesis. Using alpha 0.05 and a statistical power of 80%, the power calculations yield a sample size of at least 34 patients per group, taking into an account assumed drop-out rate of 20%.

Assignment of intervention

Allocation

Randomisation will be stratified according to the participating hospital and sex. The hospitals are grouped for stratification as A: Helsinki, Turku, Pori; B: Tampere, Jyväskylä, Kuopio, Oulu, and C: Linköping, Copenhagen. Randomisation will be performed through a web-based online system (https://www.randomize.net/) which gathers the patient information and immediately provides the treatment arm (operative / non-operative). The block size for randomisation is four. Recruitment and randomisation will continue until at least 34 patients are enrolled in each treatment group.

Blinding

The treatment modalities will be clearly and openly explained to the patients at recruitment. Participants and study investigators will not be blinded to the treatment groups. The statistician will be blinded to the treatment groups and the analysis phase will involve blinded data interpretation.

Declined cohort

Patients who are otherwise eligible but do not wish to participate, or choose to drop out from the trial, will be asked for permission to conduct a later patient-file follow-up and will be invited to participate in a follow-up study. Informed consent will be obtained from these patients. They will receive the usual care with the treatment method decided by the patient once both treatment methods have been explained. Baseline demographics, treatment modality, and the DASH at one year will be collected. Analysis of the declined

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cohort group will be done separately from the randomised controlled trial (RCT) and the results will be compared with those of the RCT.

Patient and public involvement

Patients were not involved in the design of this study. They will be informed of the results after completion of the study.

DATA MANAGEMENT AND ANALYSIS

Data management

All the data for this study will be collected on trial specific forms. Patient information forms will be uploaded to a secured cloud server (Sharefile) and the information stored in an electronic research database (RedCap) held at Turku University Hospital, TULES Division, by the study nurse. The study nurse will monitor the data for incomplete items. In case of non-adherence, the investigating physician will be contacted and the reason for non-adherence clarified. The RedCap database is protected by access codes known only to the study nurse and one of the investigators. The trial patient data will be stored for 10 years after final follow-up. All the original paper forms are stored securely by a local investigating physician or study nurse. All imaging data are stored in local electronic systems and sent to the study nurse on a CD or in electronic format after one-year follow-up.

Missing items

Missing data from questionnaires would skew the analyses and thus imputation methods will be applied. Missing individual items in DASH and PREE-F are considered missing at random (MAR) and will be substituted by the average value of other items. If the number of missing values is greater than three, the scores will not be computed. If scores at follow-up are missing or not computable, hot deck imputation will be used where

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missing score values are substituted by an average score of other patients with similar demographic and baseline data such as age, centre, gender and baseline DASH or PREE-F.

Statistical methods

After completion of the two weeks, three months and one-year follow-up, the data will be analysed by an independent statistician (blinded to the treatment groups). Intention to treat will be applied in the analyses. In case of protocol violations, analyses will be carried out for both intention to treat (ITT) and per protocol (PP) patient populations.

All demographic, pre-intervention and intervention related variables will be tabulated and summarised. All outcome measures will be summarised by visit, and in addition to absolute values, changes relative to baseline values will also be summarised where feasible. Reasons for discontinuation and study duration will be tabulated for all patients by treatment group.

The possibility of multicollinearity between study variables will be investigated in terms of the Variance Inflation Factor (VIF). Analysis of the primary outcome measure will be done using generalised linear mixed models (GLMM) suitable for repeated measures with adjusting demographic and intervention related variables. Auto-regressive covariance structure for spatiality of measurement time points is assumed to be suitable in this study setup. GLMM will also be used to analyse secondary outcomes where feasible; otherwise an alternative analysis method will be selected according to the measurement scale and variable type (eg, independent or paired data and binary, ordinal, nominal, or continuous nature). Possible analysis methods that could be used are McNemar's test, the Wilcoxon signed rank test, Cochran-Mantel-Haenszel test, Cochran-Armitage trend test, and Jonckheere-Terpstra test.

All results will be presented with 95% confidence intervals. A one-sided significance level of 0.05 will be used across the analyses. All analyses, tabulation, listings, and figures will be done with R version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria).

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Blinded data interpretation

To diminish interpretation bias, the authors and statistician will be blinded to both treatment groups when analysing the results. The approach involves developing two interpretations of the results based on blinded review of the primary outcome data (treatment A *v* treatment B). One interpretation assumes that A is the operative group, the other that A is the conservative group. After agreeing that there will be no further changes, the investigators will record their decisions and sign the resulting document. The randomisation code will be then unblinded, the correct interpretation chosen, and the manuscript finalised. [31,32]

Monitoring

Data monitoring

Patient data will be monitored weekly by the study nurse. In case of a delay or interruption in the data, the study nurse will inform the local physician, physiotherapist, and the principal investigator.

An interim analysis of the available outcome data will be performed by the trial leader when half the patients have been recruited and treated, to confirm the safety and ethical considerations of the study. In case of significantly more serious adverse events, other than fixation material removal, within any of the treatment modalities, premature discontinuation of the study will be considered. Loss of reduction or increase in displacement will not be considered a serious adverse event.

Harms

Adverse events will be documented through-out the follow-up period at scheduled and non-scheduled clinical visits. Patients and physiotherapists are urged to report any adverse events or health related issues immediately. In case of any adverse event, the local investigating physician will inform the study nurse and the principal investigator in Turku, Finland. All observed or self-reported adverse events regardless of suspected relationship to the study will be recorded. The local investigating physician will assess the

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likelihood of the adverse event having been caused by the study treatment on a six-grade causality scale (none, unlikely, possible, probable, definite, or cannot be classified). The severity of all adverse events will be graded using the Clavien-Dindo classification [33,34]. Adverse events in class 3 or higher are considered serious. All adverse events will be dealt with in a symptomatically adequate manner and the patients will be hospitalised if needed.

ETHICS AND DISSEMINATION

Ethical approval

The trial will be conducted according to the revised Declaration of Helsinki by the World Medical Association and the ICH-guidelines for good clinical trial practice. The study has been approved by the Ethics Committee of the Hospital District of Southwest Finland (7/1801/2020) and will be submitted for approval to the local Ethics Committees in Sweden and Denmark. The interventions used in this study are considered safe. Patients are not expected to experience either personal harm or benefit from participating in the trial.

Protocol amendments

No deviation should be made from the protocol without an amendment. Any amendment affecting patient care must be agreed to by the SCORE study chair (including VÄ, IL, IR, AR, KI and one investigator from each participating centre) and approved by the ethics committees before implementation. If an amendment is administrative only and does not affect patient treatment, it will not require approval by ethics committees, but must be submitted to them for their information.

Consent or assent

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Written informed consent will be obtained by the local recruiting physician at each participating centre. Consent for a patient file follow-up will be obtained from eligible patients who do not wish to participate in the trial.

Confidentiality

All patient data (paper forms and electronic database) will be handled with confidentiality. During analyses the patient's personal identification number will be blinded.

Access to data

The study nurse will maintain the register of treatment groups and patients in the trial. Patient data may be accessed by the principal investigator during the trial in case of adverse events, or by the trial leader during interim analyses. After the final 12-month follow-up of all patients, the patient data will be analysed by the principal investigator and author IR, and both analyses and patient data will be accessible to all co-investigators.

Ancillary and post-trial care

All patients enrolled in the trial may contact the local treating physician about their treated elbow at any stage of the trial. A patient may withdraw consent and discontinue the study at any time if they wish. Patients will be informed of the trial results by letter after completion of the one-year follow-up analyses.

Dissemination policy

The results of this study will be submitted for publication in peer-reviewed journals.

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DISCUSSION

In this SCORE protocol we describe a non-inferiority, randomised, controlled trial comparing the outcome of conservative treatment of displaced olecranon fractures in the elderly with operative treatment with TBW or PF. We do not aim to demonstrate that conservative treatment is better than the commonly used operative treatment, but to find out whether the results are comparable and sufficient from the patient's perspective, using patient-reported outcome measures. Hence, we chose a non-inferiority setting.

To our knowledge, there is only one ongoing RCT with the same design [16], and recently one RCT in Scotland had to be prematurely terminated due to unacceptable complication rates in the operative group [10]. Loss of reduction was the most frequent complication (6 of 11), although it was initially accepted in the conservative group by the study setup. There was no difference in any of the outcome measures between the groups. This data supports the need for further research on the role of primary conservative treatment for isolated displaced olecranon fractures in the elderly. In our study, premature discontinuation will be considered if there are significantly more serious adverse events, other than hardware removal, within any of the treatment modalities. It is worth noting that loss of reduction or increase in displacement is not considered a reason for discontinuation, contrary to Duckworth's study.

The evidence to date shows that conservative treatment might provide similar function and pain relief in the elderly compared to operative treatment [12–14] and therefore lead to a significantly lower operative and complication burden in this fragile population. Still there is a lack of RCTs and high-quality research on this matter, and no robust conclusion can yet be made. In the literature, populations have been referred to as elderly already in their sixth or seventh decade [1, 34]. Olecranon fractures in this elderly population are shown to have osteoporotic features [34]. In reality, health status and everyday functioning abilities vary widely among people in these age groups. Therefore, we chose to raise the inclusion age to 75 to avoid randomising patients who are too functionally active into the conservative treatment group, and thus to ensure the ethical aspects of non-operative treatment. Regardless of the good results of conservative

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treatment [8-10, 12], it may carry a risk of a symptomatic loss of extension strength, loss of extension range, or painful pseudo arthrosis if too much workload is applied to the arm after treatment.

We chose to compare conservative treatment with TBW and PF, as these are globally the most popular surgical methods for olecranon fractures. Several factors direct treatment towards a conservative or operative approach, one of the most important being fracture type. In the SCORE trial we chose the Mayo classification [35] which is simple and easy to use in a clinical setting, to diminish potential bias of the fracture type affecting the outcome. In the trial we will focus on displaced fractures involving the mid-portion of the olecranon where the anterior parts of the collateral ligament complexes are intact (Mayo type 2). In these type 2 fractures, ligamentous stability between the upper arm and forearm is thought to be intact, maintaining stability of the elbow regardless of the fracture [17,18]. Each Mayo fracture type is further subdivided into A: non-comminuted, and B: comminuted, and fractures in both subgroups will be included in the SCORE trial. Non-displaced Mayo type 1 fractures have widely been safely treated conservatively, and unstable fracture-dislocations (Mayo type 3) should still be treated operatively to regain joint congruency [36,37]. We recognise the uncommon risk of Mayo 2 fractures actually being Mayo 3, and subluxation or dislocation of the forearm appearing over the course of non-operative treatment. As this is a potential source of selection bias, we have chosen to follow up all patients with radiographs at two weeks to out rule this phenomenon. In case of dislocation of the forearm, the patients will be treated accordingly.

We chose primarily patient-reported outcome measures, since surgeon-reported outcomes or radiological analyses alone do not provide enough insight into how patients manage their daily life and how satisfied they are with the treatment provided. As the patients determine the success of their treatment, we will be able to distinguish which factors lead to satisfaction or dissatisfaction.

The internal validity of the trial is ensured by minimising bias using an online computer-based randomising system, appropriate statistical testing, blinded data interpretation, and an adequate sample size based on power calculation. We consider the external validity of the trial to be good, since inclusion and exclusion criteria are not too numerous, and the results will be compared with the declined cohort results.

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The results of the trial may be generalised to any other population aged 75 years or older with Mayo type 2, closed olecranon fracture, and to younger populations when the fracture shows osteoporotic features, that is, poor bone quality and a low energy trauma mechanism, and the demands for daily functioning are lowered.

The aim of the SCORE trial is to study whether conservative treatment of displaced olecranon fractures in the elderly population yields sufficient results regarding pain and function without the burden of hospitalisation and complications related to operative treatment.

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COLLABORATORS

The following persons are part of the SCORE study group: Turku University Hospital (Finland): Sanna Johansson, Pekka Karppi, Tommi Kauko and Milja Holstila. Tampere University Hospital (Finland): Bakir Sumrein. Kuopio University Hospital: Simo Miettinen. Central Finland Central Hospital (Finland): Juha Paloneva.

CONTRIBUTORSHIP STATEMENT

Design: all authors. IR drafted the manuscript, and all the protocol authors were responsible for further writing of the manuscript. All authors read and approved the final manuscript. IL is the principal investigator and VÄ is the trial leader.

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COMPETING INTERESTS

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Box 1. Inclusion and exclusion criteria

Box 2. Outcome measures

Box 3. Radiograph evaluation list

Figure 1. Flow chart of the trial

Table 1. Assessment schedule

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Box 1. Inclusion and exclusion criteria

Inclusion criteria

1. Radiologically (standard AP and lateral radiographs) confirmed, displaced (≥2mm dislocation of the joint surface) fracture of the olecranon
2. Age of patient 75 years or over at time of injury

Exclusion criteria

1. Delay of more than two weeks from traumatic event to day of intervention
2. Mayo type 3 fracture
3. Fracture continuation distal to coronoid process
4. Other acute fracture or nerve damage of ipsilateral upper limb
5. Old fracture (<6 months) or pseudoarthrosis or unhealed nerve injury of ipsilateral upper limb
6. Open fracture
7. Pathological fracture
8. History of alcoholism, drug abuse, psychological or other emotional problems likely to jeopardise informed consent
9. Patient's inability to understand written and spoken Finnish or Swedish or Danish
10. Patient's refusal to participate or cognitive incapability to provide consent
11. Patient physically unfit for surgery

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Box 2. Outcome measures
Measurements recorded at 3 and 12 months *Primary outcome measure* 1. DASH at 12 months *Secondary outcome measures* 1. DASH (other than 12 months) 2. PREE 3. Pain (VAS 0-100) 4. Satisfaction (VAS 0-100) 5. ROM of elbow 6. Extension strength of elbow compared to unaffected arm (only at 12 months) 7. Adverse events at any timepoint
DASH=Disabilities of the Arm, Shoulder and Hand; PREE=Patient Rated Elbow Evaluation; VAS=visual analogue scale; ROM=range of motion

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Box 3. Radiograph evaluation list

Primary evaluation

- Classification of fracture according to Mayo classification [14-16]

Post-operative evaluation

- Quality of reduction graded as follows
  - Excellent/exact
  - Good/satisfactory (dislocation of joint surface <2mm)
  - Poor (dislocation of joint surface ≥2mm)
  - Reduction not obtained
- Evaluation of placement of fixation materials

Evaluation at 2 weeks, 3 and 12 months

- Loss of reduction, re-displacement of joint surface ≥ 2mm (YES/NO)
- Failure of fixation (eg, tension band wire broken or out of bone)
- In non-operative treatment group, progression of dislocation compared to primary situation
- Signs of bone healing

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Figure 1. Flow chart of the trial

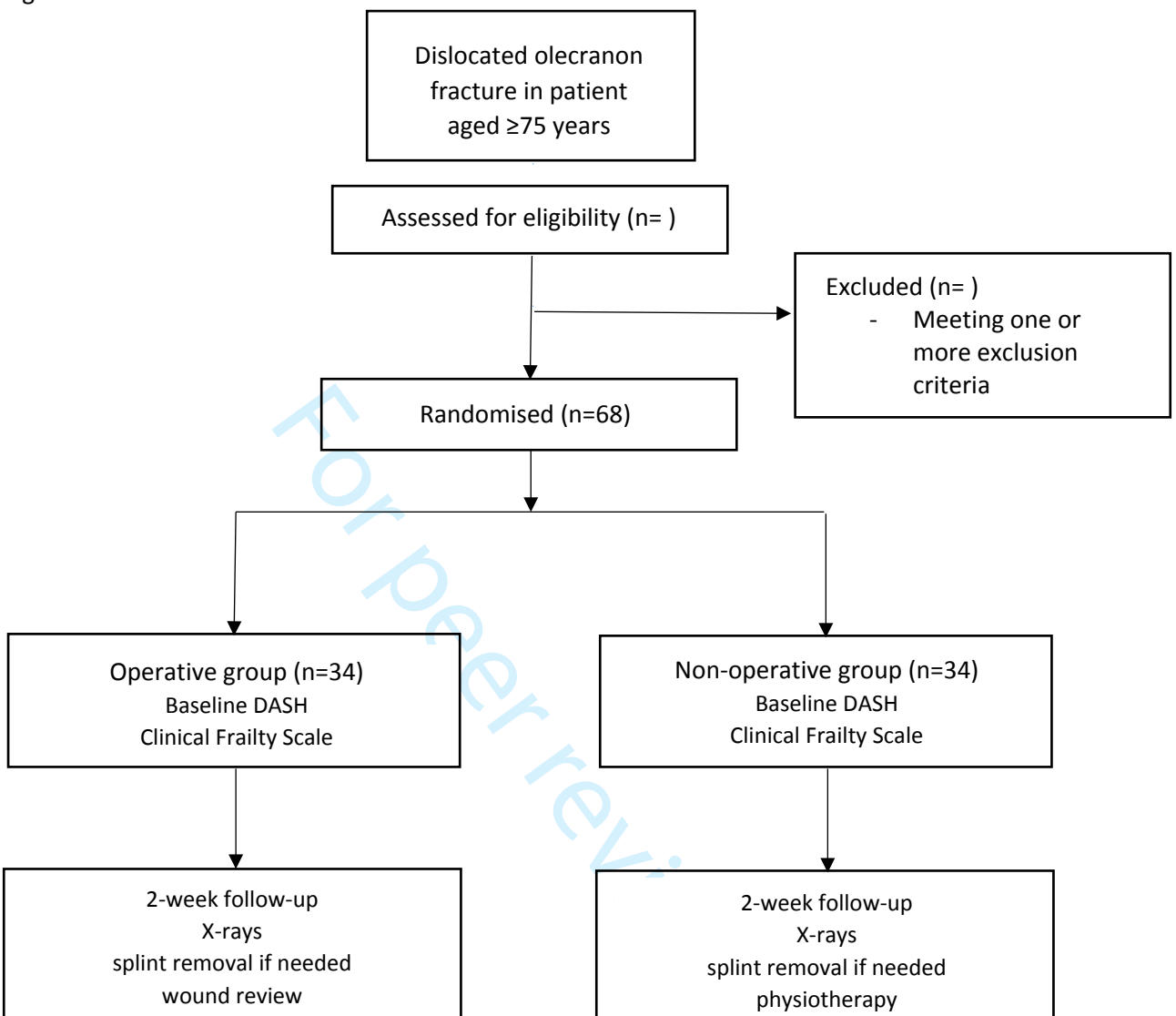

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Table 1. Assessment schedule

Assessment	ER	Screening (at local trauma centre)	Intervention (within 2 weeks of trauma)		2 weeks		3 months	12 months
			Non-operative	Operative	Non-operative	Operative		
Screening		X						
Standard information		X						
Informed consent		X						
X-rays	X			X*	X	X	X	X
Randomisation		X						
Baseline data		X						
Treatment			X	X				
Splint removal					(X)**	(X)**		
Wound review						X		
Physiotherapy					X	X		
Extension strength								X
ROM							X	X
DASH							X	X
PREE							X	X
VAS Pain							X	X
VAS Satisfaction							X	X
Adverse event form**				(X)	(X)	(X)	(X)	(X)
Discontinuation form**					(X)	(X)	(X)	(X)

ROM=range of motion; DASH=Disabilities of the Arm, Shoulder and Hand questionnaire, PREE=Patient Rated Elbow Evaluation, VAS=visual analogue scale

*Post-operatively

**If required

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4-5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	7-8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	11
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	-
	13b	For each group, losses and exclusions after randomisation, together with reasons	-
Recruitment	14a	Dates defining the periods of recruitment and follow-up	-
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	-
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	-
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	-
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15-16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-16
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Scandinavian Olecranon Research in the Elderly (SCORE): Protocol for a non-inferiority, randomised, controlled, multicentre trial comparing operative and conservative treatment of olecranon fractures in the elderly.

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Scandinavian Olecranon Research in the Elderly (SCORE): Protocol for a non-inferiority, randomised, controlled, multicentre trial comparing operative and conservative treatment of olecranon fractures in the elderly.

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Abstract

Introduction

The incidence of olecranon fractures is growing in the elderly population. The traditional operative approach is giving way among the elderly to conservative treatment, which seems to provide a comparable functional outcome with a lower complication burden. However, there is still a lack of reliable evidence to support this shift.

The objective of this trial is to investigate whether conservative treatment of displaced olecranon fractures in patients aged 75 or older yields comparable results to those of operative treatment in terms of pain and daily function.

Methods and analysis

Scandinavian Olecranon Research in the Elderly (SCORE) is a randomised, controlled, multi-centre, non-inferiority-trial. Eligible patients will be randomised to either conservative or operative treatment. The sample size will be 68 patients and allocation done at a 1:1 ratio (34 patients per group). The randomisation is stratified according to the participating hospital and patient's sex. Both groups will receive the same post-operative physiotherapy and pain management. The primary outcome is Disabilities of the Arm, Shoulder and Hand (DASH) at one-year follow-up. Secondary outcomes are pain and satisfaction measured on visual analogue scales, Patient Reported Elbow Evaluation (PREE), range of motion of the elbow and extension strength of the elbow compared to the unaffected arm. Radiographs will be taken at each follow-up. Primary analysis of the results will be conducted on an intention-to-treat basis.

Ethics and dissemination

The study protocol for this clinical trial has been approved by the Ethics Committee of the Hospital District of Southwest Finland and will be submitted for approval to the Regional Ethics Committees in Linköping, Sweden and Copenhagen, Denmark. Every recruiting centre will apply local research approvals. The results of this study will be submitted for publication in peer-reviewed journals.

Trial registration number (ClinicalTrials.gov)

NCT04401462.

Protocol version

This is the second protocol version dated on 16th of April 2020.

Key words: Intra-Articular Fractures; Ulna Fractures; Fractures, Closed; Osteoporotic Fractures; Elbow Joint; Ulna; Fracture Fixation, Internal; Open Fracture Reduction; Conservative Treatment

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Strengths and limitations of this study

- Our study will eventually demonstrate whether conservative treatment can be applied as a first choice to olecranon fractures in the elderly population.
- The multicentre setup with three participating countries increases the generalisability and external validity of this trial.
- The results of this trial are limited to cooperative patients aged 75 years or older, which will limit the external validity of the trial, as a significant proportion of patients in this age-group are non-cooperative due to dementia or other comorbidities.

INTRODUCTION

Background and rationale

Olecranon fractures account for roughly 1% of all upper extremity fractures [1]. Current epidemiological data suggest that the incidence of olecranon fractures is increasing in the elderly population after the seventh decade [1,2]. Displaced olecranon fractures have traditionally been treated operatively with osteosynthesis [3]. The most frequent operative methods for fixating a displaced olecranon fracture are tension band wiring (TBW) and plate fixation (PF). According to previous observational studies, both methods achieve adequate union and function but are also associated with a high rate of re-operations due to operative complications and removal of symptomatic fixation materials after fracture union [4–7]. Reported re-operation rates vary, reaching up to 16 – 50 % for TBW and 15 – 33 % for PF [4,8–11].

Non-operative, or conservative, treatment has been suggested as a treatment option for elderly patients in whom the function of the injured elbow does not necessarily significantly limit their daily activities. Based on data from a small retrospective series, it seems that conservative treatment could provide a similar functional outcome, with a lower complication burden, for this population [12–14]. A recent study of a US population reported a 0.66 % annual increase in non-operative management of olecranon fractures in patients aged over 75 years [15].

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To our knowledge, there is only one published and one ongoing randomised study comparing operative and conservative treatment in elderly patients [10,16]. The published trial was terminated prematurely because of an unacceptably high complication rate in the operative group [10]. As operative treatment of an isolated displaced olecranon fracture is still common in the elderly, further research is needed on the role of primary conservative treatment in this patient group.

Objectives and study hypothesis

The aim of this trial is to study the difference between operative treatment, either with TBW or PF, and conservative treatment of traumatic, displaced (Mayo 2 [17,18]) olecranon fractures in the elderly population in a non-inferiority study setting. Our null hypothesis is that conservative treatment does not yield inferior outcomes to operative treatment.

Trial design

SCORE is an ongoing, non-inferiority, randomised, controlled, multicentre trial, with two parallel treatment groups (1:1).

METHODS

Study setting

The study protocol is designed in accordance with the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials) [19]. The trial will be conducted as a multicentre study. The following hospitals participated in designing the study protocol: five university hospitals (Helsinki University Central Hospital, Turku University Central Hospital, Tampere University Hospital, Oulu University Hospital, Kuopio University Hospital) and two regional hospitals (Central-Finland Central Hospital in Jyväskylä and Satakunta Central Hospital in Pori) in Finland, and University Hospitals in Linköping, Sweden and Copenhagen,

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Denmark. All three countries have a country manager responsible for organising participation locally. Patients will be recruited at the trauma centres of the participating hospitals.

Eligibility criteria

A member of the study group will assess the eligibility of patients with displaced olecranon fractures referred to the recruiting centres. Diagnosis will be verified using conventional radiographs (standard AP and lateral radiographs). Inclusion and exclusion criteria are listed in box 1. All eligible patients will be asked to participate in the trial and written informed consent obtained. The two treatment modalities will be openly and carefully explained to the patients at recruitment. All screened patients meeting the inclusion criteria will be recorded.

Interventions

Operative group

Patients in the operative group will be prepared for surgery according to the standard of care (plexus and/or general anaesthesia based on anaesthesiologist's evaluation, antibiotic prophylaxis), and surgery will take place within two weeks of the injury. Patients will undergo surgical fixation by the preferred technique of the treating, attending or fellow surgeon (TBW or PF according to AO instructions [20]) in a manner consistent with the usual protocol of the participating institution. Post-operative protocol will include immobilisation either with a sling or a long-arm plaster splint for two weeks followed, by progressive range of motion as tolerated.

Conservative group

Conservative treatment will consist of a sling and immediate progressive range of motion as tolerated. A long-arm plaster splint may be applied for two weeks if needed for pain control and after splint removal active movements will be started as tolerated.

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In both treatment groups the patients will be referred to physiotherapy at two weeks. All patients will be prescribed painkillers, according to local care standards, as needed. Patients will be referred to a ward at their local health centre for rehabilitation if they are unable to manage at home.

Outcomes

Baseline data

After enrolment the following baseline demographics will be recorded: date of birth, sex, date of injury, mechanism of injury, dominant hand, affected side, smoking, possible diabetes or inflammatory arthritis, and whether the patient lives in a facility. In addition, a clinical frailty scale [21] and Disabilities of the Arm, Shoulder and Hand (DASH) [22,23] questionnaire will be completed at baseline for comparison of the treatment groups. Patients will be asked to answer the DASH questionnaire describing their elbow function within two weeks before the injury.

Primary outcome

Disabilities of the Arm, Shoulder and Hand (DASH)

The primary outcome compares the DASH [22,23] score at one year between treatment groups. DASH is a validated patient-reported outcome measure assessing upper-extremity related deficits and symptoms in daily life. The instrument consists of 30 items, of which at least 27 must be answered for a score to be calculated. The additional four optional items related to work, sports and music (four items each), are discarded in our study. The score ranges from 0 (no disability) to 100 (extreme disability). DASH is available and validated in several languages including Finnish [24], Swedish [25], and Danish [26]. The MCID (minimal clinically important difference) for this questionnaire is 10 points [23,27].

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Secondary outcomes

Secondary outcomes are both subjective and objective measurements. A full list of secondary outcomes is shown in box 2. Radiographs of the affected arm will also be taken at each control visit and analysed according to the detailed evaluation list shown in box 3.

Visual analogue scale; pain and satisfaction

Pain will be assessed on a 0 to 100mm visual analogue scale (VAS), from 0 on the left 'no pain' to 100 on the right 'worst possible pain'. VAS is the most frequently used assessment instrument for pain in clinical settings and is structurally simple to use [28]. Satisfaction with treatment and elbow function will be assessed similarly on a visual analogue scale, from 0 on the left 'best possible situation' to 100 on the right 'worst possible situation'.

Patient Rated Elbow Evaluation (PREE)

PREE is an elbow joint specific measure of pain and disability and is validated with psychometric methods [29]. The instrument consists of two subsections: pain with five items and function with fifteen. The subsections are computed to weigh pain and disability equally and both are scaled from 0 'best score' to 50 'worst score'. Total score is the sum of subscales. A higher score indicates more pain and functional disability.

Participant timeline

All patients will have a follow-up appointment at two weeks and three and 12 months. The detailed schedule for assessments is outlined in table 1 and the flow chart of the trial is shown in figure 1.

Sample size

The power calculations are based on assumed behaviour of the DASH questionnaire. The non-inferiority margin was determined to be MCID for this questionnaire, which is 10 points [23,27]. The standard deviation of DASH is assumed to be 15 [30]. Estimated sufficient sample size is based on simple two-sample t-test with

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one-sided alternative hypothesis. Using alpha 0.05 and a statistical power of 80%, the power calculations yield a sample size of at least 34 patients per group, taking into an account assumed drop-out rate of 20%.

Assignment of intervention

Allocation

Randomisation will be stratified according to the participating hospital and sex. The hospitals are grouped for stratification as A: Helsinki, Turku, Pori; B: Tampere, Jyväskylä, Kuopio, Oulu, and C: Linköping, Copenhagen. Randomisation will be performed through a web-based online system (https://www.randomize.net/) which gathers the patient information and immediately provides the treatment arm (operative / non-operative). The block size for randomisation is four. Recruitment and randomisation will continue until at least 34 patients are enrolled in each treatment group.

Blinding

The treatment modalities will be clearly and openly explained to the patients at recruitment. Participants and study investigators will not be blinded to the treatment groups. The statistician will be blinded to the treatment groups and the analysis phase will involve blinded data interpretation.

Declined cohort

Patients who are otherwise eligible but do not wish to participate, or choose to drop out from the trial, will be asked for permission to conduct a later patient-file follow-up and will be invited to participate in a follow-up study. Informed consent will be obtained from these patients. They will receive the usual care with the treatment method decided by the patient once both treatment methods have been explained. Baseline demographics, treatment modality, and the DASH at one year will be collected. Analysis of the declined

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cohort group will be done separately from the randomised controlled trial (RCT) and the results will be compared with those of the RCT.

Patient and public involvement

Patients were not involved in the design of this study. They will be informed of the results after completion of the study.

DATA MANAGEMENT AND ANALYSIS

Data management

All the data for this study will be collected on trial specific forms. Patient information forms will be uploaded to a secured cloud server (Sharefile) and the information stored in an electronic research database (RedCap) held at Turku University Hospital, TULES Division, by the study nurse. The study nurse will monitor the data for incomplete items. In case of non-adherence, the investigating physician will be contacted and the reason for non-adherence clarified. The RedCap database is protected by access codes known only to the study nurse and one of the investigators. The trial patient data will be stored for 10 years after final follow-up. All the original paper forms are stored securely by a local investigating physician or study nurse. All imaging data are stored in local electronic systems and sent to the study nurse on a CD or in electronic format after one-year follow-up.

Missing items

Missing data from questionnaires would skew the analyses and thus imputation methods will be applied. Missing individual items in DASH and PREE-F are considered missing at random (MAR) and will be substituted by the average value of other items. If the number of missing values is greater than three, the scores will not be computed. If scores at follow-up are missing or not computable, hot deck imputation will be used where

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missing score values are substituted by an average score of other patients with similar demographic and baseline data such as age, centre, gender and baseline DASH or PREE-F.

Statistical methods

After completion of the two weeks, three months and one-year follow-up, the data will be analysed by an independent statistician (blinded to the treatment groups). Intention to treat will be applied in the analyses. In case of protocol violations, analyses will be carried out for both intention to treat (ITT) and per protocol (PP) patient populations.

All demographic, pre-intervention and intervention related variables will be tabulated and summarised. All outcome measures will be summarised by visit, and in addition to absolute values, changes relative to baseline values will also be summarised where feasible. Reasons for discontinuation and study duration will be tabulated for all patients by treatment group.

The possibility of multicollinearity between study variables will be investigated in terms of the Variance Inflation Factor (VIF). Analysis of the primary outcome measure will be done using generalised linear mixed models (GLMM) suitable for repeated measures with adjusting demographic and intervention related variables. Auto-regressive covariance structure for spatiality of measurement time points is assumed to be suitable in this study setup. GLMM will also be used to analyse secondary outcomes where feasible; otherwise an alternative analysis method will be selected according to the measurement scale and variable type (eg, independent or paired data and binary, ordinal, nominal, or continuous nature). Possible analysis methods that could be used are McNemar's test, the Wilcoxon signed rank test, Cochran-Mantel-Haenszel test, Cochran-Armitage trend test, and Jonckheere-Terpstra test.

All results will be presented with 95% confidence intervals. A one-sided significance level of 0.05 will be used across the analyses. All analyses, tabulation, listings, and figures will be done with R version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria).

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Blinded data interpretation

To diminish interpretation bias, the authors and statistician will be blinded to both treatment groups when analysing the results. The approach involves developing two interpretations of the results based on blinded review of the primary outcome data (treatment A *v* treatment B). One interpretation assumes that A is the operative group, the other that A is the conservative group. After agreeing that there will be no further changes, the investigators will record their decisions and sign the resulting document. The randomisation code will be then unblinded, the correct interpretation chosen, and the manuscript finalised. [31,32]

Monitoring

Data monitoring

Patient data will be monitored weekly by the study nurse. In case of a delay or interruption in the data, the study nurse will inform the local physician, physiotherapist, and the principal investigator.

An interim analysis of the available outcome data will be performed by the trial leader when half the patients have been recruited and treated, to confirm the safety and ethical considerations of the study. In case of significantly more serious adverse events, other than fixation material removal, within any of the treatment modalities, premature discontinuation of the study will be considered. Loss of reduction or increase in displacement will not be considered a serious adverse event.

Harms

Adverse events will be documented through-out the follow-up period at scheduled and non-scheduled clinical visits. Patients and physiotherapists are urged to report any adverse events or health related issues immediately. In case of any adverse event, the local investigating physician will inform the study nurse and the principal investigator in Turku, Finland. All observed or self-reported adverse events regardless of suspected relationship to the study will be recorded. The local investigating physician will assess the

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likelihood of the adverse event having been caused by the study treatment on a six-grade causality scale (none, unlikely, possible, probable, definite, or cannot be classified). The severity of all adverse events will be graded using the Clavien-Dindo classification [33,34]. Adverse events in class 3 or higher are considered serious. All adverse events will be dealt with in a symptomatically adequate manner and the patients will be hospitalised if needed.

ETHICS AND DISSEMINATION

Ethical approval

The trial will be conducted according to the revised Declaration of Helsinki by the World Medical Association and the ICH-guidelines for good clinical trial practice. The study has been approved by the Ethics Committee of the Hospital District of Southwest Finland (7/1801/2020) and will be submitted for approval to the local Ethics Committees in Sweden and Denmark. The interventions used in this study are considered safe. Patients are not expected to experience either personal harm or benefit from participating in the trial.

Protocol amendments

No deviation should be made from the protocol without an amendment. Any amendment affecting patient care must be agreed to by the SCORE study chair (including VÄ, IL, IR, AR, KI and one investigator from each participating centre) and approved by the ethics committees before implementation. If an amendment is administrative only and does not affect patient treatment, it will not require approval by ethics committees, but must be submitted to them for their information.

Consent or assent

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Written informed consent will be obtained by the local recruiting physician at each participating centre. Consent for a patient file follow-up will be obtained from eligible patients who do not wish to participate in the trial.

Confidentiality

All patient data (paper forms and electronic database) will be handled with confidentiality. During analyses the patient's personal identification number will be blinded.

Access to data

The study nurse will maintain the register of treatment groups and patients in the trial. Patient data may be accessed by the principal investigator during the trial in case of adverse events, or by the trial leader during interim analyses. After the final 12-month follow-up of all patients, the patient data will be analysed by the principal investigator and author IR, and both analyses and patient data will be accessible to all co-investigators.

Ancillary and post-trial care

All patients enrolled in the trial may contact the local treating physician about their treated elbow at any stage of the trial. A patient may withdraw consent and discontinue the study at any time if they wish. Patients will be informed of the trial results by letter after completion of the one-year follow-up analyses.

Dissemination policy

The results of this study will be submitted for publication in peer-reviewed journals.

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DISCUSSION

In this SCORE protocol we describe a non-inferiority, randomised, controlled trial comparing the outcome of conservative treatment of displaced olecranon fractures in the elderly with operative treatment with TBW or PF. We do not aim to demonstrate that conservative treatment is better than the commonly used operative treatment, but to find out whether the results are comparable and sufficient from the patient's perspective, using patient-reported outcome measures. Hence, we chose a non-inferiority setting.

To our knowledge, there is only one ongoing RCT with the same design [16], and recently one RCT in Scotland had to be prematurely terminated due to unacceptable complication rates in the operative group [10]. Loss of reduction was the most frequent complication (6 of 11), although it was initially accepted in the conservative group by the study setup. There was no difference in any of the outcome measures between the groups. This data supports the need for further research on the role of primary conservative treatment for isolated displaced olecranon fractures in the elderly. In our study, premature discontinuation will be considered if there are significantly more serious adverse events, other than hardware removal, within any of the treatment modalities. It is worth noting that loss of reduction or increase in displacement is not considered a reason for discontinuation, contrary to Duckworth's study.

The evidence to date shows that conservative treatment might provide similar function and pain relief in the elderly compared to operative treatment [12–14] and therefore lead to a significantly lower operative and complication burden in this fragile population. Still there is a lack of RCTs and high-quality research on this matter, and no robust conclusion can yet be made. In the literature, populations have been referred to as elderly already in their sixth or seventh decade [1, 34]. Olecranon fractures in this elderly population are shown to have osteoporotic features [34]. In reality, health status and everyday functioning abilities vary widely among people in these age groups. Therefore, we chose to raise the inclusion age to 75 to avoid randomising patients who are too functionally active into the conservative treatment group, and thus to ensure the ethical aspects of non-operative treatment. Regardless of the good results of conservative

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treatment [8-10, 12], it may carry a risk of a symptomatic loss of extension strength, loss of extension range, or painful pseudo arthrosis if too much workload is applied to the arm after treatment.

We chose to compare conservative treatment with TBW and PF, as these are globally the most popular surgical methods for olecranon fractures. Several factors direct treatment towards a conservative or operative approach, one of the most important being fracture type. In the SCORE trial we chose the Mayo classification [35] which is simple and easy to use in a clinical setting, to diminish potential bias of the fracture type affecting the outcome. In the trial we will focus on displaced fractures involving the mid-portion of the olecranon where the anterior parts of the collateral ligament complexes are intact (Mayo type 2). In these type 2 fractures, ligamentous stability between the upper arm and forearm is thought to be intact, maintaining stability of the elbow regardless of the fracture [17,18]. Each Mayo fracture type is further subdivided into A: non-comminuted, and B: comminuted, and fractures in both subgroups will be included in the SCORE trial. Non-displaced Mayo type 1 fractures have widely been safely treated conservatively, and unstable fracture-dislocations (Mayo type 3) should still be treated operatively to regain joint congruency [36,37]. We recognise the uncommon risk of Mayo 2 fractures actually being Mayo 3, and subluxation or dislocation of the forearm appearing over the course of non-operative treatment. As this is a potential source of selection bias, we have chosen to follow up all patients with radiographs at two weeks to out rule this phenomenon. In case of dislocation of the forearm, the patients will be treated accordingly.

We chose primarily patient-reported outcome measures, since surgeon-reported outcomes or radiological analyses alone do not provide enough insight into how patients manage their daily life and how satisfied they are with the treatment provided. As the patients determine the success of their treatment, we will be able to distinguish which factors lead to satisfaction or dissatisfaction.

The internal validity of the trial is ensured by minimising bias using an online computer-based randomising system, appropriate statistical testing, blinded data interpretation, and an adequate sample size based on power calculation. We consider the external validity of the trial to be good, since inclusion and exclusion criteria are not too numerous, and the results will be compared with the declined cohort results.

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The results of the trial may be generalised to any other population aged 75 years or older with Mayo type 2, closed olecranon fracture, and to younger populations when the fracture shows osteoporotic features, that is, poor bone quality and a low energy trauma mechanism, and the demands for daily functioning are lowered.

The aim of the SCORE trial is to study whether conservative treatment of displaced olecranon fractures in the elderly population yields sufficient results regarding pain and function without the burden of hospitalisation and complications related to operative treatment.

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COLLABORATORS

The following persons are part of the SCORE study group: Turku University Hospital (Finland): Sanna Johansson, Pekka Karppi, Tommi Kauko and Milja Holstila. Tampere University Hospital (Finland): Bakir Sumrein. Kuopio University Hospital: Simo Miettinen. Central Finland Central Hospital (Finland): Juha Paloneva.

CONTRIBUTORSHIP STATEMENT

IL, IR, AR and VÄ developed the trial, IL being the principal investigator and VÄ the trial leader. IR drafted the manuscript and all the members have actively contributed in the further writing and revising the manuscript. KI is responsible for recruitment of the patients in Turku, and additionally IR, IL and AR assess the eligibility and inclusion of the patients in Turku. AL is responsible for the trial in Tampere, TL in Jyväskylä, TF in Oulu, MS in Helsinki, LA in Linköping and BO in Copenhagen. All authors have read and

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approved the final manuscript.

COMPETING INTERESTS

None of the authors, their immediate family, or any research foundation with which they are affiliated have received any financial payments or other benefits from any commercial entity related to the subject of this article.

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Figure 1. Flow chart of the trial

Box 1. Inclusion and exclusion criteria

Box 2. Outcome measures

Box 3. Radiograph evaluation list

Table 1. Assessment schedule

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Box 1. Inclusion and exclusion criteria

Inclusion criteria

1. Radiologically (standard AP and lateral radiographs) confirmed, displaced (≥2mm dislocation of the joint surface) fracture of the olecranon
2. Age of patient 75 years or over at time of injury

Exclusion criteria

1. Delay of more than two weeks from traumatic event to day of intervention
2. Mayo type 3 fracture
3. Fracture continuation distal to coronoid process
4. Other acute fracture or nerve damage of ipsilateral upper limb
5. Old fracture (<6 months) or pseudoarthrosis or unhealed nerve injury of ipsilateral upper limb
6. Open fracture
7. Pathological fracture
8. History of alcoholism, drug abuse, psychological or other emotional problems likely to jeopardise informed consent
9. Patient's inability to understand written and spoken Finnish or Swedish or Danish
10. Patient's refusal to participate or cognitive incapability to provide consent
11. Patient physically unfit for surgery

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Box 2. Outcome measures
Measurements recorded at 3 and 12 months *Primary outcome measure* 1. DASH at 12 months *Secondary outcome measures* 1. DASH (other than 12 months) 2. PREE 3. Pain (VAS 0-100) 4. Satisfaction (VAS 0-100) 5. ROM of elbow 6. Extension strength of elbow compared to unaffected arm (only at 12 months) 7. Adverse events at any timepoint
DASH=Disabilities of the Arm, Shoulder and Hand; PREE=Patient Rated Elbow Evaluation; VAS=visual analogue scale; ROM=range of motion

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Box 3. Radiograph evaluation list

Primary evaluation

- Classification of fracture according to Mayo classification [14-16]

Post-operative evaluation

- Quality of reduction graded as follows
  - Excellent/exact
  - Good/satisfactory (dislocation of joint surface <2mm)
  - Poor (dislocation of joint surface ≥2mm)
  - Reduction not obtained
- Evaluation of placement of fixation materials

Evaluation at 2 weeks, 3 and 12 months

- Loss of reduction, re-displacement of joint surface ≥ 2mm (YES/NO)
- Failure of fixation (eg, tension band wire broken or out of bone)
- In non-operative treatment group, progression of dislocation compared to primary situation
- Signs of bone healing

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Table 1. Assessment schedule

Assessment	ER	Screening (at local trauma centre)	Intervention (within 2 weeks of trauma)		2 weeks		3 months	12 months
			Non-operative	Operative	Non-operative	Operative		
Screening		X						
Standard information		X						
Informed consent		X						
X-rays	X			X*	X	X	X	X
Randomisation		X						
Baseline data		X						
Treatment			X	X				
Splint removal					(X)**	(X)**		
Wound review						X		
Physiotherapy					X	X		
Extension strength								X
ROM							X	X
DASH							X	X
PREE							X	X
VAS Pain							X	X
VAS Satisfaction							X	X
Adverse event form**				(X)	(X)	(X)	(X)	(X)
Discontinuation form**					(X)	(X)	(X)	(X)

ROM=range of motion; DASH=Disabilities of the Arm, Shoulder and Hand questionnaire, PREE=Patient Rated Elbow Evaluation, VAS=visual analogue scale

*Post-operatively

**If required

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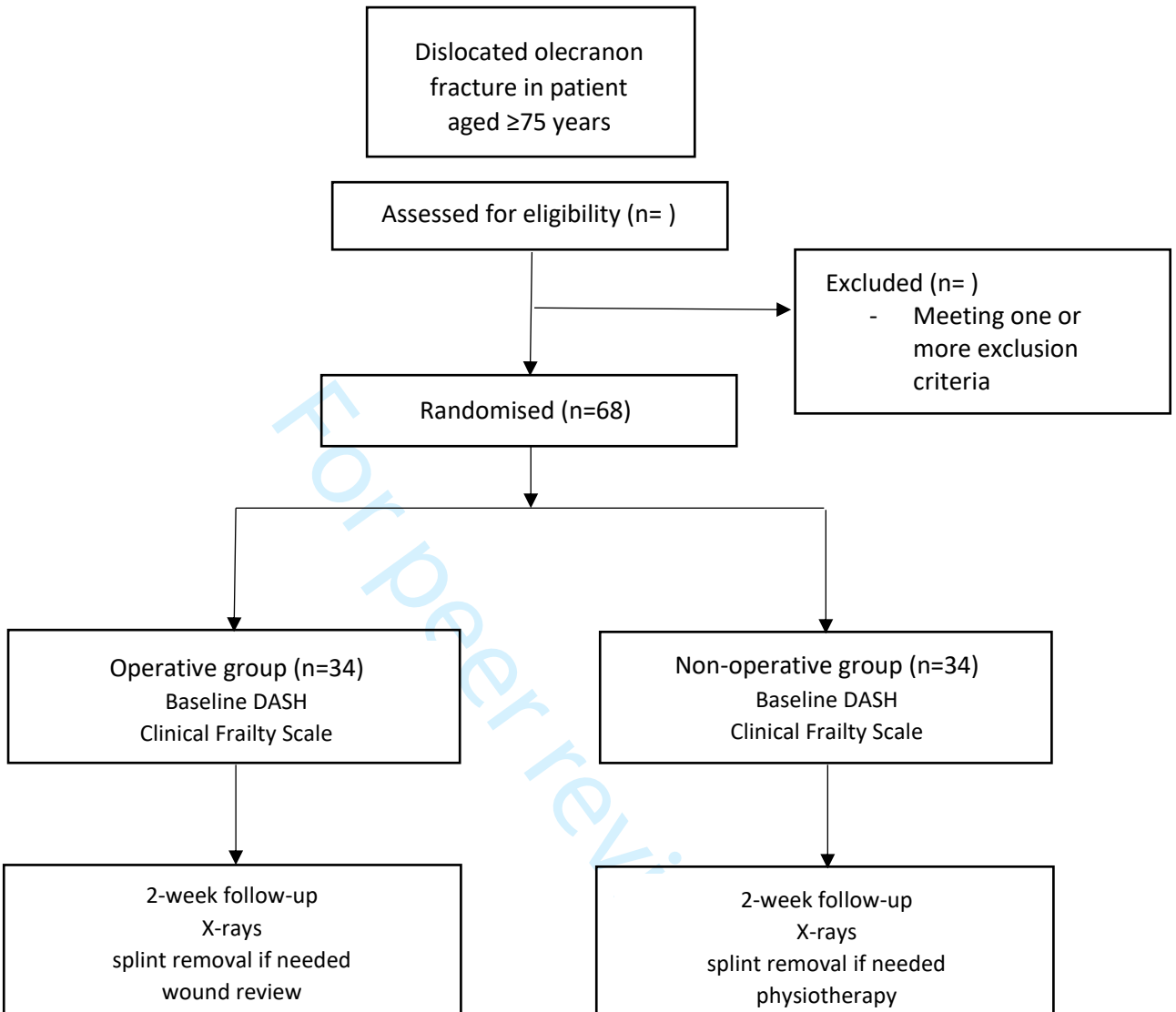

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym / Reported on page No 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry / Reported on page No 2
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier / Reported on page No 2
Funding	4	Sources and types of financial, material, and other support / Reported on page No 17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors / Reported on page No 1 and 16
	5b	Name and contact information for the trial sponsor / Not applicable
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities / Not applicable
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) / Reported on page No 9 and 11-13
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention / Reported on page No 3-4
	6b	Explanation for choice of comparators / Reported on page No 3-4 and 14

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Objectives	7	Specific objectives or hypotheses / Reported on page No 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) / Reported on page No 4
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained / Reported on page No 4-5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) / Reported on page No 5 and Box 1.
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered / Reported on page No 5-6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) / Reported on page No 12 and 14
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) / Not applicable
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial / Not applicable
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended Reported on page No 6-7
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) / Reported on page No 7, Table 1. and Figure 1.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations / Reported on page No 7-8

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Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size / Not applicable
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions / Reported on page No 8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned / Reported on page No 8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions / Reported on page No 5 and 8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how / Reported on page No 8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial / Reported on page No 11
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol / Reported on page No 9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols / Reported on page No 9-10
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol / Reported on page No 9

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Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol / Reported on page No 10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) / Reported on page No 10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) / Reported on page No 9-10
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed / Reported on page No 11
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial / Reported on page No 11
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct / Reported on page No 11-12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor / Reported on page No 11
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval / Reported on page No 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) / Reported on page No 12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) / Reported on page No 12-13
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable / Not applicable

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Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial / Reported on page No 13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site / Reported on page No 17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators / Reported on page No 13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation / Reported on page No 9 and 13
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions / Reported on page No 13
	31b	Authorship eligibility guidelines and any intended use of professional writers / Reported on page No 16
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code / Not applicable
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates / Provided as supplementary file
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable / Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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