






BMJ Open Casting in finger trap traction without reduction versus closed reduction and percutaneous pin fixation of dorsally displaced, over-riding distal metaphyseal radius fractures in children under 11 years old: a study protocol of a randomised controlled trial

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ABSTRACT

Introduction Distal radius is the most common site of fracture in children, comprising 23%–31% of all paediatric fractures. Approximately one-fifth of these fractures are displaced. Completely displaced distal metaphyseal radius fractures in children have traditionally been treated with closed reduction. Recent evidence suggests that correcting the shortening in over-riding distal metaphyseal radius fractures is not necessary in prepubertal children. To date, no published randomised controlled trial (RCT) has compared treatment of these fractures in children by casting the fracture in bayonet position to reduction and pin fixation.

Methods and analysis We will conduct an RCT to compare the outcomes of casting the fracture in bayonet position in children under 11 years of age to reduction and percutaneous pin fixation. 60 patients will be randomly assigned to casting or surgery groups. We have two primary outcomes. The first is ratio (injured side/non-injured side) in the total active forearm rotation and the second is ratio (injured side/non-injured side) in total active range of motion of the wrist in the flexion–extension plane at 6 months. The secondary outcomes will include axial radiographic alignment, passive extension of the wrists, grip strength and length of forearms and hands, patient-reported outcome QuickDASH and pain questionnaire PedsQL. Patients not willing to participate in the RCT will be asked to participate in a prospective cohort. Patients not eligible for randomisation will be asked to participate in a non-eligible cohort. These cohorts are included to enhance the external validity of the results of the RCT. Our null hypothesis is that the results of the primary outcome measures in the casting group are non-inferior to surgery group.

Ethics and dissemination The institutional review board of the Helsinki and Uusimaa Hospital District has approved the protocol. We will disseminate the findings through peer-reviewed publications.

Trial registration number NCT04323410.

Strengths and limitations of this study

- Our study is the first trial to compare the effectiveness of non-surgical treatment of paediatric distal radius fracture without reducing the fracture with reduction and surgical pin fixation.
- The cohorts of patients not willing to undergo randomisation and patients not eligible for randomisation will be included to address a common problem of randomised trials where only small subset of patients are included in the trial decreasing the external validity of the results.
- The limitation of this study is that the primary outcome is not subjective patient-reported outcome as there is no validated upper extremity score for patients of this age.

Protocol V.1.1, 29 September 2020.

BACKGROUND

Distal radius is the most common site of fracture in children and adolescents, comprising 23%–31% of all paediatric fractures.^{1–6} The reported annual incidence of distal radius fractures in children under 16 year-old in Nordic countries is around 600:100 000^{6–8} and approximately one-fifth of these fractures are displaced.⁹

Completely displaced distal metaphyseal radius fractures in children have been traditionally treated with closed reduction to restore length and alignment of the radius.^{10–14} Several surgeons prefer manipulation under anaesthesia (MUA) and percutaneous pin fixation to ensure fracture union

in satisfactory alignment.^{10 13 15–17} However, some recent evidence suggests that correcting the shortening in overriding distal metaphyseal radius fractures is not necessary in prepubertal children.^{18–21} Furthermore, up to 35° of dorsal angulation and 15° of frontal plane angulation can be expected to remodel in children under 11 years old.^{18 22–24}

Reduction of completely displaced distal radius fractures is painful and should be performed under either local or general anaesthesia, which both involve risks.^{25–27} MUA increases physician and nurse staffing requirements, length of time spent in the hospital and total cost of treatment.¹⁸ Surgery is associated with risks such as superficial and deep infection, pin migration, soft tissue lesion and physeal injury.^{13 23 28 29} On the other hand axial alignment of an over-riding distal radius fracture can be corrected and a cast applied without local or general anaesthesia in an emergency department (ED) if the fracture is left in bayonet position.¹⁸

We found one randomised controlled trial (RCT) comparing cast immobilisation to percutaneous pin fixation of displaced distal radius fractures in children²³ with neither treatment method showing clearly superior benefit. A recent Cochrane database review concludes: ‘Although percutaneous pin fixation prevents re-displacement, the effects on long-term outcomes including function are not established’.³⁰ To date, there are no RCTs comparing treatment of distal metaphyseal completely displaced radius fractures in children by casting the fracture in bayonet position to reduction and pin fixation.

Objectives and study hypothesis

We designed a pragmatic, parallel group (1:1), single centre, randomised controlled, non-inferiority trial to compare the outcome of reduction and percutaneous pin fixation in overriding distal metaphyseal radius fractures in children under 11 years of age to casting the fracture in bayonet position. We hypothesise that a treatment that involves no anaesthesia and no surgery results in a non-inferior outcome compared with a treatment that involves local or general anaesthesia and surgery. Non-inferiority of the new treatment (no reduction) with respect to the gold standard treatment (reduction) is of interest on the premise that the new treatment has some other advantages, such as no anaesthesia and no surgery and therefore reduced consumption of patients’ time and hospital resources as well as fewer adverse events (AEs). We consider non-inferiority proven if there is no difference between the two treatment groups in the primary outcome: ratio (%) of forearm rotation and wrist extension–flexion range of motion (ROM) compared with the non-affected side at 6 months.

METHODS

Study setting

The study is based on a prospective inception cohort design. The RCT will be conducted in Helsinki New

Children’s Hospital, being the tertiary referral centre for the treatment of paediatric fractures in Southern Finland with a catchment area of 2 million people. The study is conducted according to the Declaration of Helsinki.

Patient and public involvement

Patients were not involved in planning of research questions, outcome measures or design of the study. The study results will be disseminated to the study participants by mail.

Eligibility criteria

We will include 0–10-year-old (open physes) children capable of communicating in Finnish, Swedish or English with distal metaphyseal completely dorsally displaced radius fractures.

We will exclude patients with bilateral forearm injuries, Gustilo-Anderson grade II or III open fracture, Galeazzi fracture-dislocation, polytrauma, neurovascular injury of the ipsilateral upper extremity, history of a displaced forearm fracture or underlying disease affecting fracture healing.

Interventions

In the casting group, padded synthetic dorsal above-elbow and volar below-elbow splints are applied in the ED without local or general anaesthesia; the patient is lying supine with the fractured forearm in finger trap traction ([figure 1](#)). Patients will have per oral ibuprofen (15 mg/kg) and paracetamol (20 mg/kg) before the finger traps are placed to the second and third rays with the elbow in 90° flexion. Dorsal displacement and shortening of the radius are not corrected, but a gentle manipulation is attempted to regain the longitudinal forearm axis during application of the splints. The casted forearm is then supported by a collar and cuff sling ([figure 2](#)). Splints are removed in an outpatient clinic at 4 weeks.

In the surgery group, we will apply a padded dorsal above-elbow splint in the ED. Reduction and percutaneous pinning are performed under anaesthesia in the operating room by an experienced attending paediatric orthopaedic surgeon within 7 days of the injury. Reduction is performed through a small 5 mm dorsal incision with a blunt dissector if alignment is not satisfactory (less than 2 mm of shortening and displacement, angulation <10° in any plane) after three closed attempts. Pin fixation is performed with two 1.6 mm pins that do not cross at the fracture line, but penetrate both fracture fragments and engage the proximal cortices approximately 5 mm. The number of unsuccessful attempts to place the pins and the operation time are recorded. Stability of the fixation is tested manually under image intensifier by placing the wrist in full extension and flexion while the forearm is kept in neutral rotation. Pins are bent at a 90° angle approximately 1 cm from skin level and cut 1 cm from the bend to allow easy removal. Padded dorsal above-elbow and volar below-elbow splints are applied. Splints and



Figure 1 Finger traction method is used when casting the injured wrist. Dorsal displacement and shortening of the radius are not corrected but a gentle attempt is taken to regain the longitudinal axis of the forearm. A volar below-elbow splint is already in place in this picture.

pins are removed at the outpatient clinic at 4 weeks after surgery.

In both groups, if palpable tenderness is presented at time of cast removal, an additional 2 weeks of dorsal below-elbow splint is called for. The guardian removes the splint at home.

Outcomes

Subjective patient-reported outcome measures and objective clinical findings are registered during the treatment and follow-up at 1 and 4 weeks, 3 and 6 months and, 1 year post-randomisation. [Table 1](#) shows the follow-up scheme.

Primary outcomes

We have two primary outcomes: (1) ratio (injured side/non-injured side) in the total active forearm rotation and (2) ratio (injured side/non-injured side) in total active ROM of the wrist in the flexion–extension plane at 6 months ([figure 3](#)). Active forearm rotations are registered with a wrist inclinometer (Baseline measurement instruments) as the best of three separate attempts at



Figure 2 The splinted upper extremity is supported with a collar and cuff sling.



maximum supination and pronation while the child is standing, holding both elbows in 90° flexion. Similarly, active wrist extension and flexion ROM are registered as the maximum of three separate attempts at extension and flexion in neutral forearm rotation, elbows held in 90° flexion. We will consider the active forearm rotation ratio more important compared with the wrist ROM ratio if neither group will have better results in both primary outcomes. We chose an objective functional outcome over a patient-reported outcome since the primary goal of fracture care in children is to restore the function of the injured extremity. Moreover, there is no validated patient-reported outcome measure for the assessment of distal forearm fractures in prepubertal children. To validate our primary outcome, we will carry out independent assessments of the above noted outcomes by at least two assessors and calculate interobserver and intraobserver reliability of the measurements.

Secondary outcomes

Radiographic outcomes

Axial alignment of the radius is measured in anteroposterior (AP) and lateral radiographs taken at 1 and 4 weeks, 3 and 6 months, and 1 year after the fracture. To standardise the acquisition of radiographs, both AP and lateral views are taken of the forearm in neutral rotation and wrist in neutral position. Angular malalignment or deformity is recorded as the angle subtended by the intersection of two lines parallel to the axis of the radius proximal and distal to the fracture site. Ulnar variance will be assessed,

Table 1 Schedule of enrolment, interventions and assessments

	Study period						Close-out
	Enrolment	Allocation	Post-allocation				
Time point**	0–72 hours	0–7 days	1 week*	4 weeks*	3 months†	6 months†	12 months†
Enrolment							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
Interventions							
Splinting (with finger trap method)							
Reduction and pin fixation							
Removal of splints and pins				X			
Dorsal forearm splint (for 2 weeks, if needed)				X			
Assessments							
Forearms and wrists range of motion, grip strength					X	X	X
QuickDASH				X	X	X	X
PedsQL			X	X	X	X	X
Deformity measurements			X	X	X	X	X

*Follow-ups at 1 and 4 weeks are postoperatively in surgery group, and post-randomisation in casting group.

†Follow-up time points are nominal. Exact time points will be recorded and reported as median+IQR

according to the method of Hafner,³¹ at 3 and 6 months, and at 1 year.

Two attending orthopaedic surgeons and one attending paediatric radiologist, all blinded to treatment allocation and clinical data, will read all radiographs. These readers will initially meet in person to calibrate their interpretations of outcomes on a test data set before grading the trial images, then perform independent readings of coded radiographs in random order. All measurements will be recorded as an average of the three separate measurements performed. Interobserver and intraobserver reliability of the angulation is calculated using a Pearson correlation coefficient.

We will make the anonymised patient data publicly available for the scientific community (patient characteristics, outcome data and radiographs) as a supplement to the main outcome publication.

Passive extension of the wrists

We will record the passive wrist extension when the child places the palms of her hands against each other in the midline of the forearms in pronation (figure 3J).

Grip strength

Grip strength of both hands is measured with a hydraulic hand dynamometer (the Jamar, Lafayette Instrument Company, Lafayette, Indiana, USA) at 4 weeks, 3 and 6 months, and 1 year. Participants are positioned according to the standardised testing position of the

American Society of Hand Therapists: seated subject, shoulders adducted and neutrally rotated, elbow flexed at 90°, wrist at 0–30° extension and 0–15° ulnar variation.³² The best of three attempts will be recorded in kilograms.

Length of forearms and hand

Length of forearms and hand (from the tip of olecranon to the tip of the middle finger) will be measured from photographs at 3 and 6 months, and 1 year (figure 3K,L).

Patient-reported outcome measure

Subjective patient-reported outcome is assessed with QuickDASH³³ (11-item version of the disabilities of the arm, shoulder and hand score) at 1 and 4 weeks, 3 and 6 months, and 1-year follow-up. QuickDASH is a widely used and validated tool assessing upper extremity-related deficits and symptoms in daily life reported by the patient.

Pain

Pain at rest and in activities is assessed on PedsQL³⁴ questionnaire at 1 and 4 weeks, 3 and 6 months, and 1-year follow-up.

Pain medication

All patients will have the same pain management regime consisting of paracetamol 20 mg/kg and ibuprofen 10 mg/kg three times daily. Tramadol 1 mg/kg one to three times a day is prescribed for patients who cannot use ibuprofen or feel that their medication is inadequate.



Figure 3 Photographs for evaluation of forearm movements, length and shape in a 6-year-old boy taken after cast removal (casted in bayonet position in finger trap traction without anaesthesia in emergency room) at 4 weeks from the injury. These measurements are performed in this trial at 4 weeks, 3 and 6 months and 1 year. (A–B) Pronation of the forearms. (C) Supination of the forearms. (D–E) Maximal active extension of the wrists (angle between red lines). (F–G) Maximal active flexion of the wrists (angle between red lines). (H–I) Shape of forearms in medial view. (J) Maximal passive extension of the wrists (angle between red lines). (K–L) Length and shape of forearms dorsally.

Children are encouraged to take pain medication only as long as they feel pain. Length and amount of pain medication used is registered with a written questionnaire.

Overall satisfaction

At the 6-month follow-up the patient's parent(s) or guardian(s) are queried about their satisfaction with the treatment. Satisfaction with the function of the fractured upper extremity and its effect on the patient's daily living and satisfaction with the cosmetic outcome are elicited using the following questions: 'How satisfied are you with your child's affected arm in his/her daily life?' and 'How satisfied are you with the cosmetic outcome of your child's arm?' (5-step Likert scale). In addition, the overall satisfaction with the treatment is assessed with the question 'How satisfied are you with the overall treatment your child had?' (5-step Likert scale).

Participant timeline

The time schedule of enrolment, interventions, assessments and visits is shown in [table 1](#). A flow chart of the trial is presented in [figure 4](#) and randomised arm in [figure 5](#).

Safety considerations

Potential AEs will be categorised as serious AEs (SAEs) and minor AEs (MAEs). Complications due to procedural anaesthesia, iatrogenic permanent nerve injury, deep infection of the fracture site and systemic infections will be categorised as SAEs. MAEs will include, but are not limited to, cast sore, superficial infection, non-union (clinically unstable fracture at 3 months), re-fracture, implant failure, nerve palsy, or tendon injury.

If at any point an imminent problem in healing is observed, warranting a change in the treatment regimen, this will be done at the discretion of the treating physician regardless of the initial treatment allocation. AEs will be registered from the medical records by a physician not involved in the treatment of the given patient. All AEs will be treated in Helsinki New Children's Hospital by or under the supervision of experienced paediatric orthopaedic surgeons.

We will assess the long-term effect of the fracture on the function of the forearms and wrists by contacting the patients at the age of 18.

Sample size

We made the sample size calculations using non-inferiority setting with continuous outcome. We decided to use a 10% difference in the forearm and wrist ROM compared with the healthy side as our non-inferiority margin. We assumed SD of 10% based on our pilot data.²¹ Using these assumptions, the required sample size is 22 per group with 90% power to show a clinically important difference between the treatment methods with a one-sided type I error rate of 2.5%. With the assumption of 25% lost to follow-up, we decided to include 30 participants per group.

Allocation

A person not involved in the execution of the trial generated the randomisation list using block randomisation (block size not revealed to the study group before analyses). The same person prepared sealed envelopes containing the information regarding the treatment allocation (casting/surgery). Envelopes are kept in a secure, agreed location at the study centre.

After receiving informed consent, a surgeon member of the study group will open the next sequentially numbered envelope containing the treatment allocation, and the casting treatment or surgery treatment will be arranged accordingly.

RCT within a cohort design

We will introduce two separate cohorts in addition to the randomised cohort to enhance the generalisability of our findings.

Patients who are eligible for the trial but decline the randomisation are offered the possibility to participate in a concurrent observational cohort (declined cohort, [figure 6](#)). The patients and guardians can decide their preferred treatment method. They will be asked about

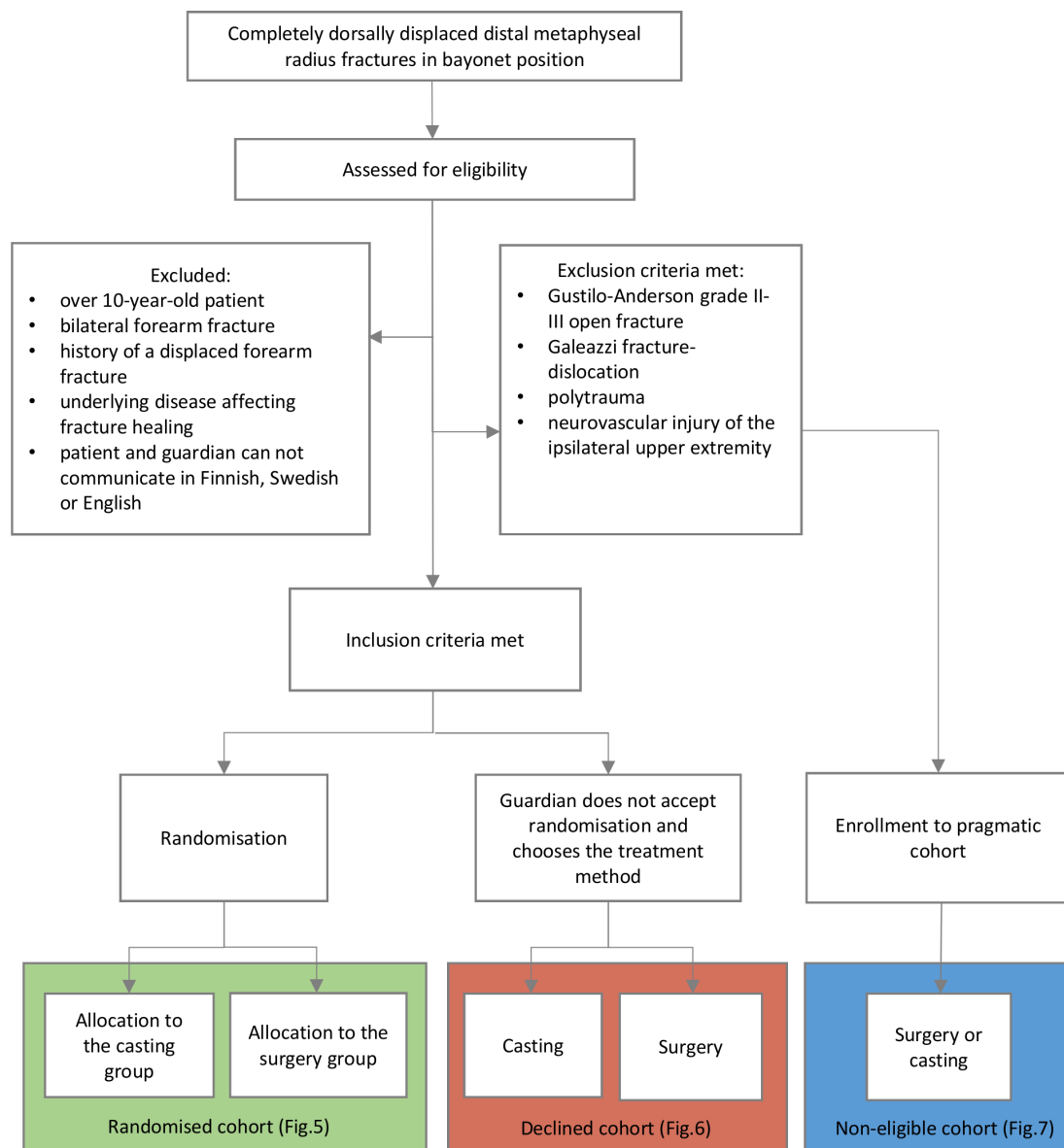


Figure 4 Flow chart of the trial with three separate cohorts: randomised cohort, declined cohort including eligible patients whose parent(s) or guardian(s) did not consent to randomisation and non-eligible cohort including patients with an exclusion criteria.

their willingness to be followed up with using the same protocol as in the randomised trial.

The patients with a forearm fracture who meet our exclusion criteria are offered the possibility of being followed up with in a separate cohort (exclusion cohort, figure 7) regardless of the treatment chosen for their injury. The cohort will be followed up with using the same follow-up protocol as in the randomised trial.

Analyses of the outcome measures in the other cohorts will be carried out separately from the randomised trial. Also, we will keep a log of the patients who are not included in any of the cohorts.

Blinding

Two orthopaedic surgeons unaware of the treatment allocation will conduct the objective measurements (forearms rotation ROM, wrists extension–flexion ROM, grip

strengths and deformity measurements). Patients will be photographed with a cast stockinet covering their wrists in order to conceal any visible scars (figure 3). The investigators will recruit the patients but will not participate in their treatment or follow-ups.

Data collection and management

The data are collected using paper forms. The questionnaires will be completed at the outpatient clinic during the control visits. Two research assistants will enter the data containing individual identification for each patient into two separate electronic databases located on a secure network drive. Data are protected with access codes known only by the research assistants. The treatment groups are coded as A and B, and their respective treatment method is known only by the research assistants. They will contact the patient and the guardian if missing, implausible or



Figure 5 Flow chart of the randomised cohort. ROM, range of motion.

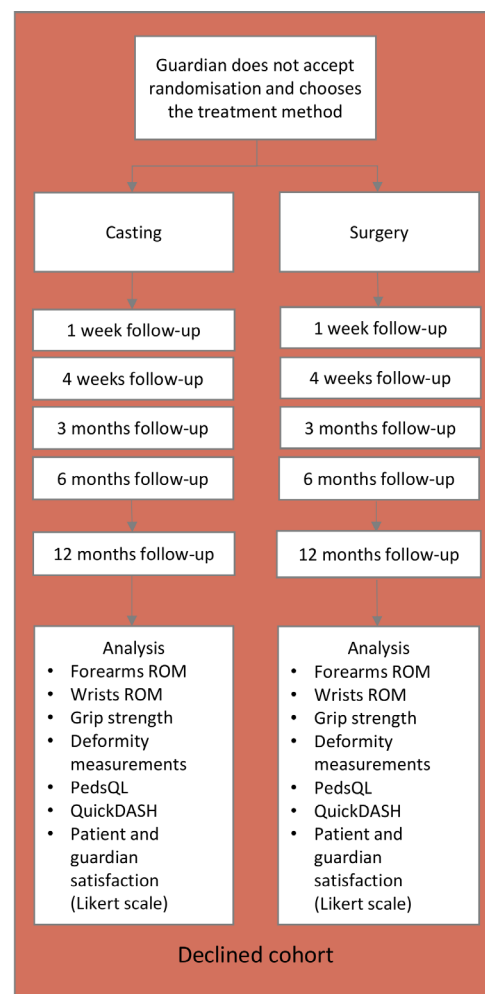


Figure 6 Flow chart of the declined cohort of eligible patients whose parent(s) or guardian(s) did not consent to randomisation. ROM, range of motion.

inconsistent data are noticed. We will compare the two databases for consistency. Inconsistencies will be checked from the original paper forms. After that the checked data will be combined and used for all data analyses.

Blinded data interpretation

We will interpret the results of the trial according to a blinded data interpretation scheme.³⁵ In brief, a statistician provides the Writing Committee with blinded results from the analyses, with the two trial arms labelled A and B. The Writing Committee then considers the interpretation of the results until a consensus is reached and the group has agreed in writing on all alternative interpretations of the findings. We will record the minutes of this meeting in a document coined statement of interpretation, which is to be signed by all members of the Writing Committee. After this common agreement is reached, the trial statistician will reveal the randomisation code and the interpretation corresponding to the correct treatment allocation will be chosen. The draft of the manuscript will then be finalised. Detailed minutes of blinded data interpretation meetings will be provided as an appendix to the primary publication.

Statistical analyses

All analyses will be performed on the intention-to-treat principle, defined as including all patients who will be randomised in the study. The descriptive statistics will be presented as means with SDs, as medians with IQR or as counts with percentages. The groups will be compared with the t-test, for continuous variables, and Pearson's χ^2 test or Fisher's exact test, for categorical variables. The primary treatment effect will be quantified with the difference between the groups in ROM ratio (pro-supination of the forearm and flexion–extension of the wrist) with the associated 95% CIs at 6 months post-randomisation. Repeated measurement results will be compared between groups with mixed effect models and an unstructured covariance structure (i.e., the Kenward-Roger method for calculating df). We consider fixed effects to include group, time and group-time interactions. Mixed models allow the analysis of unbalanced data sets without imputation; therefore, we will analyse all available data using a complete set of analyses. The AEs of the study arms will be reported descriptively. In the case of violation of the assumptions, a bootstrap-type or permutation test will

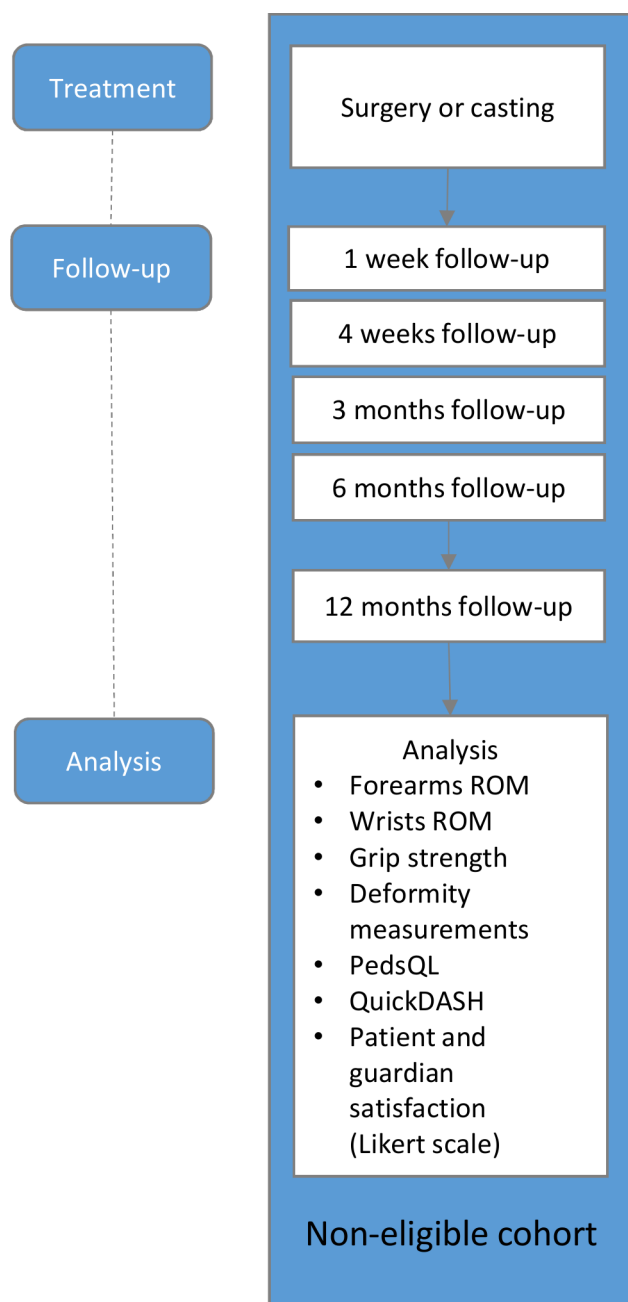


Figure 7 Flow chart of the non-eligible cohort including patients with an exclusion criteria. ROM, range of motion.

be used. Hochberg's adjustment (step-up method) will be applied to correct levels of significance for multiple testing, if appropriate. Normal distributions will be evaluated graphically and with the Shapiro-Wilk W test. Stata V.16.1 (StataCorp, College Station, Texas, USA) will be used for the analysis.

The results of the declined cohort will also be tested and reported using the statistical methods described above.

Data safety and monitoring committee

A data safety and monitoring committee (DSMC) will be convened to oversee data collection and integrity, and with the steering committee (SC) will approve the statistical analysis plan and research protocol. The integrity

of trial data will be monitored by regularly scrutinising the electronic data collection and source for omissions and errors by blinded members of the research staff. The DSMC will be independent from the study sponsor and will be convened to monitor AEs in order to ensure the safety of participants. The frequency of DSMC meetings and the stopping rules will be defined a priori in a charter, in consultation with its members. The DSMC will have access to unblinded data and AEs (after coding). Given the nature of the trial, participants could be exposed to risks that may justify early termination of the trial. Data on complications will be recorded as outcomes and the DSMC will assess their severity and frequency. Members of the DSMC will not be involved in the study, will not have any conflict of interest and will not benefit in any way from the results of this trial. The DSMC will make recommendations to the chair of the SC, who will be responsible for making the final decision on the recommendations. If necessary, this may be done in consultation with the ethics committee.

Harms

We will report all harms and complications of the treatment when reporting the results of this trial. The safety considerations section describes the categorisation of the harms as major and minor complications.

Ethics and dissemination

Research ethics approval

This trial will be conducted according to the Declaration of Helsinki. The protocol has been approved by the institutional review board of the Helsinki and Uusimaa Hospital District (HUS/2345/2019), and the trial has been duly registered at ClinicalTrials.gov.

Protocol amendments

All modifications of the study protocol will be communicated by updating the trial registry (ClinicalTrials.gov).

Consent

The recruiting doctor will obtain the informed consent. The consent form is filled out by the guardian of the patient.

Confidentiality

Databases will be maintained in secure storage at the research centre for 15 years after completion of the study.

Access to data

After the final data set is formed from the primary data, data set access will be limited to the statistician and the authors of the final publication. The codes of the RCT arms will be known only to the two research assistants until the blinded data interpretation has taken place.

Ancillary care

The participants will be treated according to our best knowledge during and after the trial. Patients will not receive any compensation for any harms from the

treatment. The Finnish Patient Insurance Centre will provide compensation for treatment injuries.

Dissemination policy

The findings of this study will be disseminated through peer-reviewed publications and conference presentations. Patients participating in the trial will be sent a letter with information on the results after the results are published.

DISCUSSION

In this protocol paper, we describe the execution of a non-inferiority RCT that aims to assess whether treatment of over-riding distal metaphyseal radius fractures with a cast immobilisation and no associated reduction results in non-inferior outcomes and no increased risk of harms as compared with subjecting these patients to surgical reduction and pin fixation under anaesthesia. To our knowledge, this is the first RCT comparing leaving the radius in bayonet position to reduction and percutaneous pin fixation in the treatment of over-riding distal metaphyseal radius fractures in children.

Some of the methodological choices warrants brief elaboration. First, to increase the generalisability of our findings, we chose a non-operative comparator that is as simple (and hopefully, feasible) as possible: the finger trap method chosen for this trial should represent a very simple procedure that can be executed even in general practice. As for the surgical comparator, closed reduction and percutaneous pin fixation is the current 'gold standard' surgical treatment of these fractures. It requires anaesthesia, and the children are exposed to radiation during the procedure. Accordingly, if our trial shows that the (functional) outcomes of participants treated non-operatively are within the chosen non-inferiority margin of those treated surgically, we will consider our findings supportive of treating these fractures non-operatively based on the aforementioned other clear benefits. To support our conclusions, the intra-rater and inter-rater reliabilities of primary and secondary outcomes are also registered, published and discussed, respectively.

The choice of the primary outcome(s) for our trial proved to be a challenge. Non-unions and malunions, the outcomes typically used in fracture trials in adults, are quite uncommon in paediatric fracture patients in general and particularly so for closed metaphyseal fractures in children. Moreover, patients with even quite dramatic healed malalignment are usually pain-free and rarely complain of any functional deficits in activities of daily living. To make our choice of a primary outcome even more complicated, there are no validated patient-reported outcome measures for this age group. With all this in mind, we deemed the function and the appearance of the injured limb as the most relevant outcomes to both the patient and her/his guardian, and accordingly, chose our primary outcomes to quantify these traits. Although the patient-reported outcomes were deemed secondary, we will collect and use them to provide support for our

primary inferences or to prompt new insights for future studies (explanatory and/or hypothesis-generating). Having said all this, one can obviously criticise our decision to choose an assessment of the deficits in the ROM of the forearm and wrist as our primary outcome, as it is a non-validated outcome. To safeguard against potential unjustified inferences, we plan to assess the reliability of these measurements made from photographs (intra-rater and inter-rater agreement).

Expectations

We expect that ratios between forearms in the total active forearm rotation and in total active ROM of the wrists in the flexion–extension plane in the casting group are non-inferior to surgery group at 6 months. The recruitment began on 30 June 2020 and we expect to complete the recruitment in 2024.

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Contributors TL, JP, AS, JK, HK, LR and YN developed the trial, TL being the principal investigator. TL drafted the manuscript and all the members have actively contributed in the further writing of the manuscript. TL and YN assessing the eligibility and inclusion of the patients to the trial. HK is responsible for the statistical methodology. All authors have read and approved the final manuscript.

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