STATISTICAL ANALYSIS PLAN

Version 1.0

Date: 21.3.2026

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

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Original protocol: 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
Version 1.1
Date 29.9.2020

Trial registration: ClinicalTrials.gov (NCT04323410)

SAP REVISION HISTORY

Date	Timing	Drafted/revised by	Version number	Description of amendments
21.3.2026	Prior to last follow-up visit	Topi Laaksonen Lasse Rämö Yrjänä Nietosvaara	1.0	First draft of SAP based on original trial protocol

Signatures

Date	Role	Name	Signature
21.3.2026	Author of the SAP and senior statistician responsible	Ville Ponkilainen	
21.3.2026	Chief investigator	Topi Laaksonen	

INTRODUCTION

Background

This trial is 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.

Objective

The primary objective of the trial is to determine whether casting without reduction is noninferior compared with reduction and percutaneous pin fixation based on the ratio (%) of (1) forearm rotation and (2) wrist extension–flexion range of motion (ROM) compared with the non-affected side at 6 months. The noninferiority margin was defined as a between-group difference of 10% for each of the coprimary endpoints.

STUDY METHODS

The trial design, eligibility criteria, randomization, sample size calculations, outcomes and framework are described in the published trial protocol[1].

Timing of outcome assessments

Co-primary endpoints (Forearms and wrists range of motion) are collected at 3 months, 6 months and 12 months.

Secondary outcomes are assessed as follows:

- Grip strength and forearm length at 3 months, 6 months and 12 months.
- QuickDASH at 1 week, 4 weeks, 3 months, 6 months and 12 months.
- PedsQL and sagittal and coronal plain radiographs at 1 week, 4 weeks, 3 months, 6 months and 12 months.
- Overall satisfaction at 6 months

Timing of final analysis

Primary timepoint will be 6-month time point. All analyses are conducted after 12-month follow-up visit.

STATISTICAL PRINCIPLES

This Statistical Analysis Plan presents the analyses for the trial primary manuscript. The manuscript will include 12-month follow-up data for the trial.

Protocol amendments

This SAP is based on the final protocol version 1.1 (date 29.9.2020).

The statistical testing will differ from the original protocol in following ways:

1) Baseline differences between groups will not be statistically tested[2 3].

2) Multiplicity bias will not be adjusted, as the primary comparison follows a prespecified hierarchical testing strategy. The secondary comparisons will be considered only to be supportive, explanatory or hypothesis-generating (or both), which is why multiplicity is not considered a problem.

Confidence intervals and p values

Confidence intervals will be reported at the 95% level. All statistical tests will be two-sided, with a significance threshold of $p < 0.05$.

Sample size

Sample size calculations were conducted using non-inferiority design with continuous co-primary endpoints. We decided to use a 10% between-group 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[4]. 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.

Estimands

Table 1. Estimands of the trial. Primary analyses will follow the treatment policy estimand framework[5-7]. Sensitivity analyses will be applied according to the hypothetical estimand strategy to address the occurrence of intercurrent events.

	Treatment policy estimand	**Hypothetical estimand**
	Effect of surgery vs no reduction regardless of intercurrent events	Effect of surgery vs no reduction if all patients receive only the allocated interventions
Estimand		
Population	Overriding distal metaphyseal radius fractures in children under 11 years of age	
Treatment conditions	Casting without prior reduction vs closed reduction and percutaneous pinning, regardless subsequent surgical intervention(s)	Casting without prior reduction vs closed reduction and percutaneous pinning, targeting only participants that do not undergo subsequent surgeries.
Co-primary endpoints	Ratio (%) of (1) forearm rotation and (2) wrist extension–flexion range of motion (ROM) compared with the non-affected side at 6 months	
Summary measure	Between-group difference in means	
Intercurrent events		
Subsequent surgery	Treatment policy strategy (effect regardless of whether some patients undergo subsequent surgeries)	Hypothetical strategy (effect if any of the patients do not undergo subsequent surgeries)
Analysis		
Where applied	Primary analysis	Sensitivity analysis
Implications	Analysis will be done by including all randomized patients in the analysis according to their assigned treatment arm (ITT analysis population), in conjunction with a repeated-measures mixed-model	Analysis will be done by including all randomized patients in the analysis according to their assigned treatment arm but censoring outcome data at the point an intercurrent event occurred.

TRIAL POPULATION

Baseline patient characteristics

Baseline demographic and clinical characteristics will be summarized descriptively by treatment group as presented at Table 1. For continuous variables, data will be presented as mean (standard deviation [SD]) for approximately normally distributed variables, and as median (interquartile range [IQR]) if the distribution is non-normal. Dichotomous variables will be reported as counts (percentages). The normality of continuous variables will be assessed using visual inspection of histograms and the Shapiro–Wilk test in cases of uncertainty.

ANALYSIS

Co-primary endpoints

We have two co-primary endpoints:

1. ratio (injured side/ non-injured side) of the total active forearm rotation
2. ratio (injured side/non-injured side) of total active ROM of the wrist in the flexion–extension plane

Active forearm rotations are registered with a wrist inclinometer as the best of three separate attempts at 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.

Analysis hierarchy for coprimary endpoints

The coprimary endpoints will be evaluated using the following testing strategy:

First, total active forearm rotation at 6 months post-randomisation will be tested. If the lower bound of the confidence interval for the between-group difference does not exceed the prespecified non-inferiority margin of 10%, the groups will be considered non-inferior, and testing will proceed to the second coprimary endpoint. Non-inferiority will be concluded only if both coprimary endpoints demonstrate non-inferior between-group differences. In that case, casting without prior reduction will be considered non-inferior to closed reduction and percutaneous pinning for metaphyseal radius fractures in children under 11 years of age.

Secondary endpoints

The secondary endpoints include:

1. Radiographic outcomes (Axial alignment of the radius (degrees) and ulnar variance (mm), continuous) at 1 week, 4 weeks, 3 months, 6 months and 12 months.
2. Passive extension of the wrists compared with the uninjured side (degrees, continuous) at 3 months, 6 months and 12 months.
3. Grip strength (Jamar hydraulic hand dynamometer, kilograms, continuous) at 3 months, 6 months and 12 months.
4. Forearm length (measured in mm and compared with the uninjured side, continuous outcome) at 3 months, 6 months, and 12 months.
5. Function (QuickDASH without Work Module, 0-100, higher score represents more symptoms, continuous) at 4 weeks, 3 months, 6 months and 12 months.

The questionnaire will be completed jointly by the participant and their parent, and a single score will be reported.

6. Pain (PedsQL Pain Questionnaire: 1. current pain 2. worst pain in last 7 days, 0-10, higher score represents higher pain, continuous) at 1 week, 4 weeks, 3 months, 6 months and 12 months. The questionnaire will be completed independently by both the participant and their parent, and participant- and parent-reported scores will be reported separately.
7. Satisfaction, assessed by the parent (satisfaction with functional outcome, satisfaction with cosmetic outcome, satisfaction with overall treatment, 5-point Likert, higher score indicates higher satisfaction, continuous) at 6 months.

Primary analysis

The co-primary endpoints, ratio (%) of (1) forearm rotation and (2) wrist extension–flexion range of motion at 6 months, will be analysed using a repeated-measures mixed-model (RMMM) with an unstructured covariance structure.

Fixed effects will include treatment group (A or B) and time point (3 months, 6 months and 12 months), and a random effect for individual patients. Effect estimates will be presented as adjusted least-squares means with 95% confidence intervals (CIs).

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 corresponding 95% CIs at 6 months post-randomisation. The noninferiority margin is 10% difference between the treatment groups.

Secondary analysis

All secondary endpoints are treated as continuous variables and will be analysed similar to the primary comparison using RMMM model. As some of the secondary endpoints (radiographic measurements, quality of life and function) are also measured at 1 week and 4 weeks post-randomisation, all available time points for the respective outcome measure will be included in the model.

The secondary treatment effects will be quantified with the difference between the groups with the corresponding 95% CIs at 6 months post-randomisation.

Missing data

Missing data for continuous outcome measures will not be imputed, as we are assuming data are missing at random, consistent with the underlying assumption of the model[8]. The number of missing data items, including withdrawals and losses to follow-up at each time point, will be reported descriptively.

Multiplicity

Multiplicity bias will not be adjusted, as the primary comparison follows a prespecified hierarchical testing strategy. The secondary comparisons will be considered only to be supportive, explanatory or hypothesis-generating (or both), which is why multiplicity is not considered a problem.

Sensitivity Analyses

All primary and secondary comparisons will follow *treatment policy estimand* framework[5-7]. We plan to perform sensitivity analysis according to the hypothetical estimand strategy if any of the participants undergo intercurrent event (subsequent surgery):

Analysis will be done by including all randomized patients in the analysis according to their assigned treatment arm but censoring outcome data at the point an intercurrent event occurred.

Sensitivity analysis will cover primary and secondary as described above.

Harms

Adverse events in this study will be categorised as serious adverse events (SAEs) and minor adverse events (MAEs). SAEs include but are not limited to 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.

Adverse events will be reported descriptively as counts with percentages.

Blinded Analysis

The primary analysis will be conducted using blinded data interpretation. Treatment groups will be labeled using coded identifiers (e.g., Treatment A and Treatment B). All statistical analyses and interpretations will be completed based on these blinded group assignments before unblinding occurs.

Statistical software

Analyses will be conducted using R software, version 4.4.1 (R Foundation for Statistical Computing, Vienna Austria). Data cleaning will be performed using the R packages janitor, dplyr, and tidyr; analyses will be conducted using lme4, emmeans, and geepack; and figures will be generated using ggplot2.

PROPOSED FIGURES AND TABLES

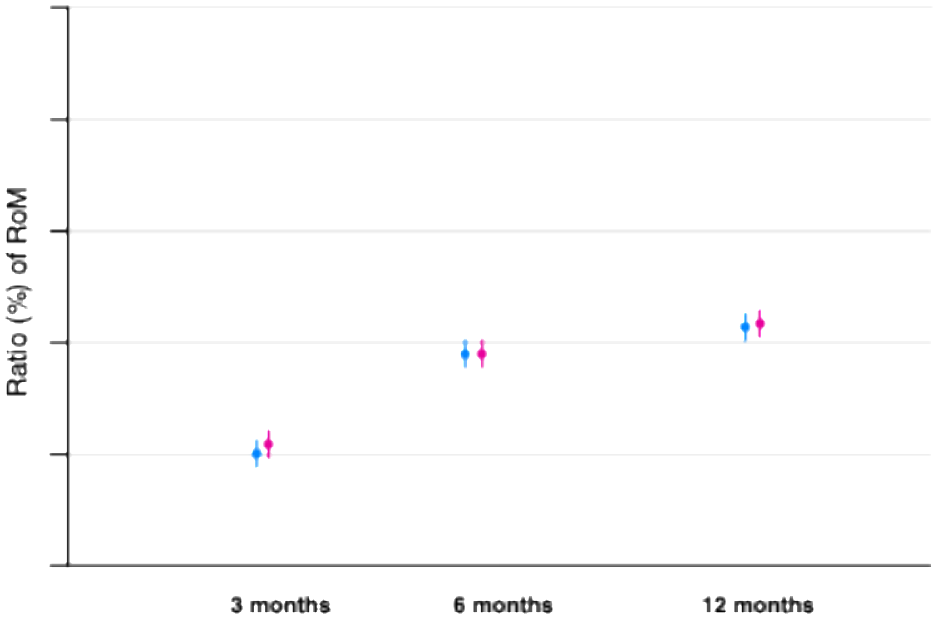

Figure 1. The trajectory of both co-primary endpoint measures will be displayed as a point plot. Each point represents the least-squares mean with error bars indicating the confidence intervals at the corresponding time point by group, derived from repeated-measures mixed model (RMMM).

Table 1. Primary results at 6 months

	Group A	Group B	Between-group difference
	Mean (SD)	Mean (SD)	Adjusted mean difference (95% CI)
Co-primary outcomes			
Forearm rotation[a]			
Wrist flexion-extension RoM[a]			
Secondary outcomes			
Radiographic measurements			
Axial alignment of radius			
Ulnar variance			
Passive extension of wrist[a]			
Forearm length			
Grip strength			
Function (QuickDASH)			
Pain (PedsQL)			
Current pain, assessed by child			
Current pain, assessed by parent			
Worst pain in last 7d, by child			
Worst pain in last 7d, by parent			
Satisfaction			
Function			
Cosmesis			
Overall treatment			

[a] measured as a ratio compared to uninjured side

Table 2. Complications as counts with percentages at 12 months.

	Group A	Group B	RR (95% CI)
Serious adverse events			
Minor adverse events			

REFERENCES

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4. Laaksonen T, Puhakka J, Stenroos A, et al. Cast immobilization in bayonet position versus reduction and pin fixation of overriding distal metaphyseal radius fractures in children under ten years of age: a case control study. *J Child Orthop* 2021;15(1):63-69. doi: 10.1302/1863-2548.15.200171
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