

Trial comparing a non-operative and standard operative treatment for children's fractures above the elbow in the low- and middle-income context

Submission date 24/07/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/06/2025	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Supracondylar fractures just above the elbow are common in children and can cause disability throughout life. It is known that some treatments are safer and some are more effective than others. Two treatments are considered to be particularly safe and effective. No study has ever looked at these treatments head to head and no prospective study of these treatments has been done in a low- or middle-income country (LMIC). The study aims to compare these treatments in the LMIC context.

Who can participate

Children aged 3 to 10 years sustaining this specific but common fracture above the elbow and presenting to one of the eight study centres in Ethiopia

What does the study involve?

If after explanation and patient advice sheet a guardian wishes for their child to be entered into the study, and signs the written consent, their child will be randomly allocated to receive one or other of the two recognised treatments. The two recognised treatments are:

1. Non-operative using lateral straight arm traction
2. Operative using closed reduction and percutaneous pinning

After treatment the child will be followed as an outpatient for 6 months, and the guardian will respond to a telephone questionnaire after 3, 6 and 12 months.

What are the possible benefits and risks of participating?

As with other studies the patients are expected to benefit from the study-observer effect whether they have the operative or non-operative treatment option. In normal practice patients may be discharged between 6 and 12 weeks after treatment whereas this study requires a 6-month outpatient attendance (transport will be paid), and a questionnaire response up to 12 months.

Where is the study run from?

The study lead is in Hawassa University Hospital (Ethiopia). External advice and support will come from Chester, UK, and Zurich, Switzerland.

When is the study starting and how long is it expected to run for?

February 2024 to July 2026

Who is funding the study?

AO Alliance Foundation (Switzerland)

Who is the main contact

1. Prof. William James Harrison, jharrison@ao-alliance.org

2. Dr Mengistu Gebreyohanes, mengistugy@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof William James Harrison

ORCID ID

<https://orcid.org/0000-0001-7229-0041>

Contact details

Countess of Chester NHS Foundation Trust

Chester

United Kingdom

CH21UL

+44 (0)356 0000

jharrison@ao-alliance.org

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRB/287/16

Study information

Scientific Title

Effectiveness of straight arm traction versus operative treatment for displaced pediatric supracondylar humerus fractures: a randomized controlled trial

Acronym

STOPUS

Study objectives

Non-operative treatment of children's supracondylar humeral fractures using lateral straight arm traction is not inferior to operative treatment using closed reduction and percutaneous pinning.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 20/06/2024, Hawassa University College of Medicine and Health Sciences IRB (Hawassa University, Ethiopia, Hawassa, 1560 CMHS, Ethiopia; +46 (0)8209290; antenehg@hu.edu.et), ref: IRB/287/16

Study design

Multi-centre interventional single-blind randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Paediatric supracondylar humeral fractures

Interventions

Randomisation (computer generated) between two accepted treatment options to test for non-inferiority in the low- and middle-income country context. The two recognised treatments are:

1. Non-operative using lateral straight arm traction
2. Operative using closed reduction and percutaneous pinning

Intervention Type

Procedure/Surgery

Primary outcome(s)

Current primary outcome measure as of 15/08/2024:

Limb function as measured by the PROM PROMIS Parent Proxy Upper Extremity Short Form 8a version 3.0 administered by blind independent reviewer at 12 months after injury.

Previous primary outcome measure:

Quality of life measured using PROMIS 7+2 pediatric PROM administered as a telephone questionnaire using blind independent technicians to patient guardians at 3, 6 and 12 months after injury

Key secondary outcome(s)

Current secondary outcome measures as of 15/08/2024:

1. Limb function measured by the PROM PROMIS parent proxy upper extremity short form 8a version 3.0 administered by a blind independent reviewer at 6 months after injury.
2. Global health as measured by the PROM PROMIS parent proxy 7+2 version 3.0 administered by a blind independent reviewer at 6 and 12 months after injury.
3. Parent satisfaction with treatment as measured by a visual analogue scale administered by the treating surgeon team at 3 and 6 months after injury.
4. Complications as measured by a checklist administered by treating surgeons 3 and 6 months after injury
5. Flynn's criteria of elbow form and function administered by treating surgeons 3 and 6 months after injury

Previous secondary outcome measures:

1. Carrying angle and range of movement at the elbow measured using Flynn's criteria of elbow function clinically in person by treating surgeons at 3 and 6 months after injury
2. Complications measured in person by treating surgeons at 3 and 6 months after injury. Specific recording of nerve injury (radial, median including anterior interosseous, ulnar), vascular injury or compromise, and infection.

Completion date

31/07/2026

Eligibility

Key inclusion criteria

1. Patient attending hospital with fresh supracondylar humeral fracture
2. Age range 3 to 10 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

10 years

Sex

All

Key exclusion criteria

1. Open fracture
2. Patient with critical ischaemia
3. Delayed presentation after 72 hours of injury

Date of first enrolment

01/08/2024

Date of final enrolment

31/07/2025

Locations**Countries of recruitment**

Ethiopia

Study participating centre

Hawassa University Hospital

Hawassa

Ethiopia

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Study participating centre

Bahir Dar University Hospital

Ethiopia

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Study participating centre

St Paul's Hospital

Addis Ababa

Ethiopia

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Study participating centre

Black Lion Hospital

Addis Ababa

Ethiopia

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Study participating centre

Mekele University Hospital
Ethiopia
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Study participating centre
Gondar University Hospital
Ethiopia
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Study participating centre
Jijiga University Hospital
Ethiopia
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Study participating centre
Alert Hospital
Addis Ababa
Ethiopia
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Sponsor information

Organisation
AO Alliance Foundation

Funder(s)

Funder type
Charity

Funder Name
AO Alliance Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Mengistu Gebreyohanes (mengistugy@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/06/2025	25/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes