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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
Recruiting

Registration date
25/07/2024

Overall study status
Ongoing

Last Edited
25/06/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

Participant information sheet
Created in Amharic and relevant local languages but not web based

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 measure

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.

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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

Secondary outcome measures
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

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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.

Overall study start date
01/02/2024

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

Age group
Child

Lower age limit
3 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
220

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
00000

Study participating centre
Alert Hospital
Addis Ababa
Ethiopia
00000

Sponsor information

Organisation
AO Alliance Foundation

Sponsor details
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Sponsor type
Charity

Website
https://ao-alliance.org/

Funder(s)

Funder type
Charity

Funder Name
AO Alliance Foundation

Results and Publications

Publication and dissemination plan
Planned publication in an open access peer reviewed journal

Intention to publish date
31/07/2027

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