

# A trial comparing traditional surgical approach with Ilizarov soft tissue distraction in the treatment of clubfoot that has never had prior treatment and will not respond to casting

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|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>20/01/2017   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                       | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>07/02/2017 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>10/04/2018       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |
|                                        |                                                       | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Clubfoot is a deformity of the foot and ankle that some babies are born with. If treated early, the position and function of the foot can generally be corrected quite easily. Many children however do not receive this treatment which can lead to pain and difficulty walking as they grow up (neglected clubfoot). This is a particular problem in poor countries where people are unable to easily access medical care. It is a problem for individuals and families involved as in many cultural settings it excludes individuals and families from social integration causing indignity. Between the ages of two and ten, most children with clubfoot can be treated using a technique called serial casting (applying and removing a series of lightweight casts on the affected area), however this does not generally work in children over 12. This study is looking at two treatments that can be used for difficult-to-treat feet. The first involves surgery to remove bones and joints within the foot to straighten it and stiffen it and the second involves putting wire pins through the bones and connecting them up to a device (Ilizarov fixator) that gradually pulls on the bones to line them up. The aim of this study is to compare the effectiveness of these treatments.

### Who can participate?

Children aged 2-16 who have a neglected clubfoot that could not be treated with serial casting.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive treatment with surgery to release the tight tendons in the foot and then, in a second procedure, removing bones and joints within the foot to straighten it and stiffen it, followed by use of a cast for 3-5 months. Those in the second group undergo treatment using an Ilizarov fixator. This involves putting wire pins through the bones and connecting them up to a device that gradually pulls on the bones to line them up. After the foot is straight it is put into a plaster cast. At the start of the study and after one year, participants in both groups complete a range of assessments to measure their pain levels and foot function.

What are the possible benefits and risks of participating?

Participants who take part benefit from receiving treatment that they would not have otherwise had access to. There are no notable risks of participating other than the general risks associated with having foot surgery.

Where is the study run from?

CURE Ethiopia Children's Hospital (Ethiopia)

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

May 2015 to January 2019

Who is funding the study?

CURE International UK (UK)

Who is the main contact?

Mr Tim Nunn

tim.nunn@cure.org

## Contact information

### Type(s)

Scientific

### Contact name

Mr Tim Nunn

### Contact details

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## Additional identifiers

### Protocol serial number

mosi.nrerc/0084/2015

## Study information

### Scientific Title

A trial comparing traditional surgical approach with Ilizarov soft tissue distraction in the treatment of clubfoot that has never had prior treatment and will not respond to casting

### Acronym

NRCT

### Study objectives

Null hypothesis:

There is no difference between functional outcomes of joint sparing compared with joint invasive approaches at 1 year when treating neglected resistant clubfeet in young children.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethiopian Ministry of Science and Technology National Research Ethics Review Committee (NRERC), 17/12/2015, ref: mosi.nrerc/0084/2015

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Neglected clubfoot

### **Interventions**

Participants are randomised to one of two groups using sealed envelope randomisation in a 1:1 ratio.

Group 1: Participants undergo surgery with Percutaneous soft tissue releases of the tendo Achilles in a 3 step manner (Hoke) then the application of the Ilizarov apparatus foot frame. This involves 2 tibial rings and 2 foot 1/2 rings fixed with tensioned wires. The frame is adjusted daily by 1mm and after correction the frame is removed, a long leg cast is applied and 6 weeks later a Tibialis anterior tendon transfer performed.

Group 2: Participants undergo a staged triple arthrodesis. This involves initial soft tissue releases of the posterior tendinous structures and posterior ankle joint capsulotomy, plantar fascia release and abductor hallucis release at the distal tendinous portion. 6 weeks later a triple arthrodesis is performed. This involves bone resection and fusions of the talo-calcaneal, talo-navicular and calcaneao-cuboid joints.

Follow up involves clinic review, pedobarography and questionnaires. And takes place after 1 year.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Current primary outcome measure as of 10/04/2018:

Laaveg-Ponseti score (a questionnaire that includes patient assessments of satisfaction, function and pain assessments and physician assessments of foot position motion and gait) at 1 year after treatment

Original primary outcome measure:

Foot function is measured using the Oxford foot and Ankle score at baseline and 1 year

### **Key secondary outcome(s)**

Current secondary outcome measures as of 10/04/2018:

1. Footprint area and peak pressures are measured using a pedobarograph at baseline and 1 year
2. Function is assessed using the Roye score and Bangla score at baseline and 1 year
3. Foot function is measured using the Oxford Foot and Ankle Questionnaire (OxFAQ) score at baseline and 1 year

Original secondary outcome measures:

1. Footprint area and peak pressures are measured using a pedobarograph at baseline and 1 year
2. Function is assessed using the Roye score and Bangla score at baseline and 1 year

### **Completion date**

01/01/2019

## **Eligibility**

### **Key inclusion criteria**

1. Age 2-16
2. Neglected clubfoot
3. Idiopathic
4. Not responding to casting

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

2 Years

### **Upper age limit**

16 Years

### **Sex**

All

### **Key exclusion criteria**

1. Neuromuscular clubfoot
2. Syndromic clubfeet

### **Date of first enrolment**

01/11/2016

**Date of final enrolment**

01/09/2017

## Locations

**Countries of recruitment**

Ethiopia

**Study participating centre**

CURE Ethiopia Children's Hospital

Next to Hamle 19 Park

Addis Ababa

Ethiopia

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## Sponsor information

**Organisation**

CURE International UK

**ROR**

<https://ror.org/00q1rv339>

## Funder(s)

**Funder type**

Charity

**Funder Name**

CURE International UK

## Results and Publications

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date