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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

Submission date
20/01/2017

Recruitment status
No longer recruiting

Registration date
07/02/2017

Overall study status
Completed

Last Edited
10/04/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 devise 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/05/2015

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

Age group
Child

Lower age limit

2 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
25

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

Sponsor details
35-43 Lincoln's Inn Fields
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Sponsor type

Charity

ROR
https://ror.org/00q1rv339

Funder(s)

Funder type
Charity

Funder Name
CURE International UK

Results and Publications

Publication and dissemination plan
Planned publication in an International Orthopaedic high-impact journal.

Intention to publish date
01/01/2019

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