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A clinical trial comparing casting and skin traction versus frame fixation to repair shin bone fractures

Submission date
30/08/2018

Recruitment status
No longer recruiting

Registration date
03/09/2018

Overall study status
Completed

Last Edited
28/01/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Injury results in the death of approximately 5.8 million people each year, as well as severe disability for survivors, the majority of which occur in developing countries. A large proportion of these injuries are fractures or broken bones, with one of the commonest being broken leg bones. Sierra Leone is a country in West Africa and is one of the world's poorest countries with a very weak healthcare system. There are limited treatment options for patients who break the bones in their legs and many of them have to live with disability or die from their injuries. This study aims to examine the treatment of broken tibia (shin) bones in the main government hospital of Freetown (Sierra Leone's capital), called Connaught Hospital. At present the treatment options for these fractures are casting with plaster of Paris and skin traction. For many of these fractures, this treatment is less than ideal, and often can result in prolonged hospital stay and poor function during and after treatment.

Who can participate?
Inpatients with broken shin bones in Connaught Hospital, Freetown

What does the study involve?
20 patients will undergo treatment as usual, with plaster of Paris and skin traction. The results of this will be compared with 20 patients who will receive a surgical intervention known as Ilizarov frame fixation. This involves a surgical procedure where the fracture is held in place by metal pins and an external frame to hold the broken pieces of bone steady while they heal. We think the benefit of this will be that the patient can walk quicker, get home from hospital quicker and have better bone healing and quality of life in the end. A large part of the study will look to see if the frame can be put in safely in Connaught and what are the costs and benefits of the frame compared to the current treatment. We hope the results will contribute to the implementation of a cost-effective and sustainable fracture fixation service in the future.

What are the possible benefits and risks of participating?
Patients will have to pay for their care like normal, including their time in hospital, doctor and nurse bills and food. The trial will pay for their follow-up visits at 30-days and 3-months,

including transport expenses to get to the hospital. If the participant is in the group that receives the current treatment option, there are no particular added risks by taking part in this study. They will still need the follow-up appointments. If the participant is in the group receiving the operation and frame, there are additional risks associated with the surgical procedure and aftercare of the frame itself. These will be discussed in more detail during an extra operation specific consent process. However, participants in this group may be able to walk quicker, get home from hospital quicker and have better bone healing and quality of life.

Where is the study run from?
Connaught Hospital, Freetown (Sierra Leone)

When is the study starting and how long is it expected to run for?
April 2018 to June 2020

Who is funding the study?
National Institute for Health Research using Official Development Assistance (ODA) funding (UK)

Who is the main contact?
William Bolton
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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
version 1.3

Study information

Scientific Title
Feasibility of Ilizarov frame fiXation for closed Tibial fractures in Sierra Leone

Acronym
FIXT

Study objectives
Using the Ilizaorv frame external fixation system can improve angular deformity in closed tibial fractures at 3 months post-intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial is currently being reviewed by The University of Leeds School of Medicine Research Ethics Committee (MREC 18-001). We plan to submit the trial to the Sierra Leone Ministry of Health and Sanitation Scientific Research Ethics Committee in August 2018, and will not begin the trial until ethical approval has been granted from both these ethics bodies.

Study design
Interventional single-centre before-and-after non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Closed tibial fractures

Interventions
The trial is a before and after study design with 40 patients in total (20 in each arm). The first 20 receive treatment as usual, which consists of plaster of Paris with or without traction and a total hospital stay up to 6 weeks. The second 20 receive operative fixation with the Ilizarov frame,

which requires one operation and the expected length of hospital stay is a few days. The frame remains on as long as clinically needed, but typically 10-12 weeks for tibial fractures. All participants receive a follow-up at 30 days and 3 months post entry into the trial.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The fracture angular deformity at 3 months post-management, as defined by overall angular deformity on long leg alignment views via anteroposterior and lateral plain radiographs

Secondary outcome measures
The following will be assessed after 30 and at 3 months post-management:
1. Length of hospital stay, defined as the time between registration into trial and actual discharge date or censored at end of trial follow-up
2. Date of being medically fit for discharge, defined as the time between entry into the trial and clinical assessment concluding the patient is medically fit for discharge or censored at end of trial follow-up
3. Time to fully weight bear, defined as the ability to mobilise unaided based on clinical evaluation by a member of the caring team
4. Time to patient rerun to work or pre-morbid responsibilities (e.g. caregiving) if not employed and is self-defined by patient
5. Patient self-reported functional status, assessed using the Lower Limb Functional Index (LLFI)
6. Quality of life, assessed using the EuroQol-5D (EQ5D)

Overall study start date
01/04/2018

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Able to provide written informed consent
3. Diagnosis of a closed diaphyseal tibial fracture with no intraarticular extension, and amenable to limb-sparing surgery following radiographic investigation
4. Fractures must have an angular deformity of 10 degrees or greater, or a displacement of greater than 50% in any plane at entry into the trial
5. Fracture sustained within 3 weeks of eligibility assessment
6. American Society of Anaesthesiologists (ASA) physical status ≤3
7. Capable of completing required questionnaires at time of consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Open fractures
2. Undisplaced fractures
3. Concurrent fractures of any bone requiring operative or traction management (concurrent fracture of the ipsilateral fibular is permitted)
4. Pre-existing diabetes via finger prick capillary blood glucose check
5. Pre-existing neuropathy via clinical examination of a doctor
6. Pre-operative compartment syndrome via clinical examination of a doctor
7. Sickle cell disease by past medical history
8. Immunosuppression by past medical history
9. Pathological fractures by radiographic and clinical examination
10. Lower limb lymphatic filariasis by clinical examination
11. Any previous involvement in the before or after arm of the trial
12. Patients who reside outside of the Western region catchment area

Date of first enrolment
01/11/2018

Date of final enrolment
01/09/2020

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Connaught Hospital
Lightfoot Boston Street, Tower Hill, Western Area
Freetown
Sierra Leone
GPS: 8.4873,-13.2388

Sponsor information

Organisation
The College of Medicine and Allied Health Sciences (COMAHS)

Sponsor details
University Secretariat Building,
University of Sierra Leone,
A.J. Momoh Street,
Tower Hill
Freetown
Sierra Leone
GPS: 8.4873,-13.2388

Sponsor type
University/education

Website
http://www.usl.edu.sl/college-of-medicine-and-allied-health-sciences-comahs

ROR
https://ror.org/045rztm55

Funder(s)

Funder type
Not defined

Funder Name
The National Institute for Health Research

Results and Publications

Publication and dissemination plan
To maintain the scientific integrity of the trial, data will not be released prior to the first publication of the analysis of the primary endpoint, either for trial publication or oral presentation purposes. Publications relating to methodological issues in FIXT may be published prior to publication of the primary endpoint analysis. Any publicity or publication from the trial must comply with the publication policy within the collaboration agreement between the University of Leeds NIHR Global Health Research Group in Surgical Technologies (GHRG) (Co-Directors Profs David Jayne and Julia Brown) and College of Medicine and Allied Health Sciences (COMAHS), University of Sierra Leone, Freetown (contact is the study PI Dr Ibrahim Bundu). Fully anonymized research data will be used in publications both in peer-reviewed scientific journals and national and international research meetings, as well as published on the research group websites.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other