ISRCTN11137938 https://doi.org/10.1186/ISRCTN11137938

Can making an L-shaped cut in the bone so that the blood supply is maintained shorten the time taken to lengthen the leg following surgery to remove dead tissue in patients with infection of the shin bone (tibial osteomyelitis)?

Submission date
04/09/2018

Recruitment status
No longer recruiting

Registration date
22/10/2019

Overall study status
Completed

Last Edited
06/12/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteomyelitis is infection and inflammation of the bone or bone marrow. Surgery and open fractures are the main causes of this disease. Long-lasting (chronic) osteomyelitis often causes death (necrosis) of soft tissues (for example muscle) and bone. The dead bone can provide a place for harmful bacteria to grow and hide from antibiotics in the blood. The first step of treating chronic osteomyelitis is cutting out all infected bone and soft tissue, which often causes massive bone loss and limb shortening. Distraction osteogenesis is a process used to lengthen the long bones of the body. The bone is separated into two sections, and the two ends of the bone are gradually moved apart using a frame attached to the sections with metal pins, allowing new bone to form in the gap. This technique has gradually become a widely used treatment for osteomyelitis of the shin bone (tibia). But one of the most common problems of this method is the long treatment time, which means there is greater potential for complications, such as infection complications. In order to shorten the treatment time and reduce complications, we use L-shaped corticotomy (vertical bone splitting) to reserve half of the bone with its blood supply.The we gradually move the splitting part to fill the gap caused by the infected bone removal.

Who can participate?
Adult patients with chronic tibial osteomyelitis

What does the study involve?
All the patients will undergo the technique of L-shaped corticotomy with partial bone sliding. A researcher will perform a clinical assessment and make a record of any complications every month. Functional outcome and quality of life will be collected post-operation.

What are the possible benefits and risks of participating?
The potential benefits are shorter treatment time and fewer complications. The potential risks include infection and failure of the bone to grow.

Where is the study run from?
Orthopaedic Department, Shanghai Jiao Tong University Affiliated Sixth People's Hospital

When is the study starting and how long is it expected to run for?
August 2007 to July 2015

Who is funding the study?
Orthopaedic Department, Shanghai Jiao Tong University Affiliated Sixth People's Hospital

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
L-shaped corticotomy with bone flap sliding in the management of chronic tibial osteomyelitis: Surgical Technique and Clinical Results

Study objectives
The technique of L-shaped corticotomy with vascularized bone flap sliding can preserve blood supply from both the osteotomic and debridement area to the largest possible extent and increase the bone contact area, thus shortening the duration of Ilizarov distraction device and solving the problems caused by traditional method of bone transport.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Shanghai Jiao Tong University Affiliated Sixth People's Hospital, 10/02 /2017, 2017-167

Study design
Observational retrospective study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic tibial osteomyelitis

Interventions
L-shaped corticotomy with bone flap sliding

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The external fixation time (EFT) represented the total number of days the external fixator was attached to the bone, calculated at the last follow-up
2. The external fixation index (EFI), defined as the duration of external fixation in days divided by the total amount of lengthening in cm, calculated at the last follow-up

Secondary outcome measures
1. Pin tract inflammation was made according to Dahl's grading every month after surgery
2.. Bone healing criteria according to the criteria of Paley at the last follow-up
3.. Bone functional results according to the criteria of Paley at the last follow-up
4. Rate of bridging of at least three out of four cortices assessed by X-ray prior to the segmental excision and then at 2-weekly intervals.

5. Impact of the musculoskeletal condition assessed using Short-form Musculoskeletal Function Assessment (SMFA) questionnaire at 2, 12 and 25 weeks
6. Quality of life assessed using the 36-item Short Form Health Survey (SF36) at 2, 12 and 25 weeks
7. Pain assessed using a visual analogue scale (VAS) with results taken in line with standard care

Overall study start date
05/08/2007

Completion date
15/07/2015

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Patients with chronic osteomyelitis only involving the anterior tibial cortex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8

Total final enrolment
8

Key exclusion criteria
1. Diffuse osteomyelitis affecting both anterior and posterior cortices of the tibia
2. Severe neuro-vascular damage or mental disease or any other conditions which might lead to lack of cooperation

Date of first enrolment
07/08/2007

Date of final enrolment
12/11/2014

Locations

Countries of recruitment

China

Study participating centre
Orthopaedic Department, Shanghai Jiao Tong University Affiliated Sixth People's Hospital
600 Yishan road, Shanghai 200233
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Sponsor information

Organisation
Orthopaedic Department, Shanghai Jiao Tong University Affiliated Sixth People's Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220qvk04

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Orthopaedic Department, Shanghai Jiao Tong University Affiliated Sixth People's Hospital

Results and Publications

Publication and dissemination plan
We will report the study results 1 year after the trial has ended.

Intention to publish date
29/10/2019

Individual participant data (IPD) sharing plan
The data will be available on request from Pei Han (Hanpei_cn @163.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/02/2019	06/12/2021	Yes	No