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UK FixDT: Fixation of Distal Tibia fractures

Submission date
07/01/2013

Recruitment status
No longer recruiting

Registration date
10/01/2013

Overall study status
Completed

Last Edited
24/05/2018

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The tibia (shinbone or shankbone) is the most commonly broken major bone in the leg. Injuries usually require hospital admission, frequently require surgery and result in prolonged periods (months) away from work and social activities. The treatment of displaced, extra-articular fractures of the distal tibia (lower third) remains controversial. These injuries are difficult to manage due to the limited soft tissue cover, poor vascularity of the area and proximity of the fracture to the ankle joint. Infections, non-union and malunion are well-recognised complications. The aim of this study is to find out whether there is a clinical and cost-effectiveness difference between two techniques for the operative fixation of fractures of the distal tibia: locking-plate fixation and intramedullary nail fixation.

Who can participate?
All patients aged 16 years or over presenting at the trial centres with an isolated, acute fracture of the distal tibia are potentially eligible to take part in the trial.

What does the study involve?
Participants will be randomly allocated to either intramedullary nailing or locking-plate fixation. Both of these operations are widely used within the NHS and all of the surgeons in the chosen centres will be familiar with both techniques. A research associate will perform a clinical assessment and make a record of any early complications at 6 weeks after the operation and an x-ray will be taken. A further clinical assessment and x-ray will also be taken at 12 months after the operation to detect late complications. Participants will complete questionnaires at 3 months, 6 months and 12 months after the operation.

What are the possible benefits and risks of participating?
The patient may benefit from internal fixation of the fracture. The risks associated with this study are predominantly the risks associated with the surgery: infection, bleeding and damage to the adjacent structures such as nerves, blood vessels and tendons. Participants in both groups will undergo surgery and will potentially be at risk from any/all of these complications. There is no data to suggest that the risk is greater in one group or another. We believe that the overall risk profile is similar for the two interventions but assessment of the number of complications in each group is a secondary objective of this trial.

Where is the study run from?
The University of Warwick in collaboration with University Hospitals Coventry and Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2013 to February 2017

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/136/04, Version 2.0

Study information

Scientific Title
UK FixDT - a randomised controlled trial for patients with a displaced fracture of the distal tibia, is there a clinical and cost-effectiveness difference between 'locking' plate fixation and intramedullary nail fixation

Acronym
UK FixDT

Study objectives
Null hypothesis: There is no difference in the Disability Rating Index (DRI) at 6 months after injury between adults with a displaced fracture of the distal tibia treated with 'locking'-plate fixation versus intramedullary nail fixation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Coventry & Warwickshire, 06/11/2012, REC ref: 12/WM/0340

Study design
Multi-centre randomised clinical 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Distal Tibia Fractures / Injuries & Accidents

Interventions
Comparing two techniques for the operative fixation of fractures of the distal tibia.

Intramedullary nailing
The intramedullary nail is inserted at the proximal end of the tibia and passed down the centre of the bone in order to hold the fracture in the correct (anatomical) position. The reduction technique, the surgical approach, the type and size of the nail, the configuration of the proximal and distal inter-locking screws and any supplementary device or technique will be left entirely to the discretion of the surgeon as per standard clinical practice.

'Locking' plate fixation
The 'locking' plate is inserted at the distal end of the tibia and passed under the skin on the surface of the bone. Again, the details of the reduction technique, the surgical approach, the type and position of the plate, the number and configuration of fixed-angle screws and any supplementary device or technique will be left to the discretion of the surgeon. The only

stipulation is that fixed-angle screws must be used in at least some of the distal screw holes - this is standard practice with all distal tibia 'locking' plates.

Intervention Type
Procedure/Surgery

Primary outcome measure
To quantify and draw inferences on observed differences in the Disability Rating Index between the trial treatment groups at 6 months after injury

Secondary outcome measures
1. To quantify and draw inferences on observed differences early functional status at 3 months and later functional status at 12 months
2.To quantify and draw inferences on observed differences in the radiological outcomes: non-union, mal-alignment and shortening
3. To identify any differences in health-related quality of life between the trial treatment groups in the first year after the injury. EQ-5D; The EQ-5D is a validated, generic health-related quality of life measure consisting of 5 dimensions each with a 3-level answer possibility. Each combination of answers can be converted into a health utility score. It has good test-retest reliability, is simple for patients to use, and gives a single preference-based index value for health status that can be used for broader cost-effectiveness comparative purposes.
4. To determine the complication rate of intramedullary nail fixation versus 'locking'-plate fixation in the first year after the injury. all complications will be recorded, including malunion, delayed/non-union, infection, wound complications, vascular and neurological injury and venous thrombo-embolism. A record will also be kept of any other surgery required in relation to the index fracture, including removal of any metalwork.
5. To investigate, using appropriate statistical and economic analytical methods, the resource use, costs and comparative cost effectiveness of intramedullary nail fixation versus 'locking'-plate fixation

Olerud and Molander (OMAS) is a self-administered patient questionnaire. It is a good outcome tool for assessing symptoms after an ankle fracture. The score is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and work/activities of daily living. The scoring system correlates well with parameters considered to summarise the results after this type of injury and is therefore recommended for use in scientific investigations.

Overall study start date
01/03/2013

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Aged 16 years or over, either sex
2. Any fracture which involves the distal tibial metaphysis - defined as a fracture extending within 2 Muller squares of the ankle joint
3. In the opinion of the attending surgeon, the patient would benefit from internal fixation of the fracture

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Minimum of 320

Key exclusion criteria
Current exclusion criteria as of 03/02/2014:
1. In the opinion of the attending surgeon, there is a contraindication to intra-medullary nailing
2. The fracture is open
3. There is a contra-indication to anaesthesia
4. There is evidence that the patient would be unable to adhere to trial procedures or complete postal questionnaires

Previous exclusion criteria:
1. In the opinion of the attending surgeon, there is a contraindication to intra-medullary nailing
2. The fracture is open with a Gustillo grade of more than 1
3. There is a contra-indication to anaesthesia
4. There is evidence that the patient would be unable to adhere to trial procedures or complete postal questionnaires

Date of first enrolment
01/03/2013

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Warwick
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ROR
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Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/09/2015		Yes	No
Results article	results	14/11/2017		Yes	No
Results article	results	01/05/2018		Yes	No