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A randomised clinical pilot trial comparing intramedullary nailing with plate and screw fixation in the treatment of patients with an acute fracture of the distal tibia

Submission date
14/07/2010

Recruitment status
No longer recruiting

Registration date
14/07/2010

Overall study status
Completed

Last Edited
17/09/2013

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7111

Study information

Scientific Title

Acronym
Management of Distal Tibia

Study objectives
The aim of the project is to perform a pragmatic pilot trial comparing two modes of treatments of distal tibia fractures. The two commonest treatment modalities are intramedullary nailing (where the nail is inserted in the tibia across the fracture) and screw and plate fixation. There is no agreement in the literature as to which treatment is best. The literature has shown that complications following the treatments mentioned above are very similar between the two modalities (infection, mal-union and non-union and re-operations) but no one has looked at the actual function of the patients following one treatment compared to the other. The objective is therefore to compare the two modes of treatments for distal tibia fractures, in terms of patient disability rating and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 8/H1210/1)

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
1. Intramedullary nailing: a nail is inserted in the tibia across the fracture
2. Screw and plate fixation: a plate and screw are used to fix the fracture

Follow-up length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Disability Rating Index. The principle measurement of the primary outcome measure will be at one year after injury.

Secondary outcome measures
1. American Orthopaedic Foot and Ankle Society Hind foot Scale at 3, 6 and 12 months post-injury
2. Complications including wound dehiscence, infection, mal-union, non-union, reoperations, time in hospital and return
3. EQ-5D at 3, 6 and 12 months post-injury
4. Olerud and Molander ankle score at 3, 6 and 12 months post-injury

Overall study start date
01/03/2008

Completion date
30/09/2010

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned Sample Size: 24

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2008

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
Gibbet Hill Road
Coventry
England
United Kingdom
CV4 7AL

Sponsor type
University/education

Website
http://www2.warwick.ac.uk

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Research organisation

Funder Name
AO Foundation (Switzerland)

Alternative Name(s)
AO Trauma, AO

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

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?
Results article	results	01/05/2012		Yes	No