

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	☐ Prospectively registered
Registration date 14/07/2010	Overall study status Completed	☐ Protocol
Last Edited 17/09/2013	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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)

Primary study design

Interventional

Study design

Single centre randomised interventional treatment trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

30/09/2010

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation

University of Warwick (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

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