ISRCTN54687269 https://doi.org/10.1186/ISRCTN54687269

Comparing a nail placed within the fibula (calf bone) to plates and screws in surgical stabilisation of unstable ankle fractures in adults

Submission date
13/03/2020

Recruitment status
No longer recruiting

Registration date
14/04/2020

Overall study status
Completed

Last Edited
15/05/2020

Condition category
Surgery

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

Plain English summary of protocol
Unstable ankle fractures are most commonly managed with surgery using plates and screws. There can be complications related principally to wound healing and infection, and prominent metalwork. In patients with poor skin condition, such as those aged over 65, and diabetics, an alternative device, the fibular nail, has been shown to achieve reduction and stability with a lower rate of such complications. The aim of this study was to compare the outcome of fibular nail with plate fixation for unstable fractures of the ankle in a younger cohort of patients.

Background and study aims
Ankle fractures are common injuries. When the fracture is unstable it requires surgery, and the most common way to fix the bones is with plates and screws. There can be problems from the wound and the plate. In this study, the investigators aimed to compare this established technique with a newer alternative: the use of a fibular nail which avoids both potential problems.

Who can participate?
Adult patients with unstable ankle fractures

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will have standard fixation surgery using plates and screws. The other will have fixation surgery using the fibular nail.

What are the possible benefits and risks of participating?
Participants in the fibular nail group may have a lower rate of wound- and metalwork-related complications. They will, however, still have an operation and therefore there will inevitably still be a small risk of surgical and anaesthetic complications.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
May 2010 to March 2015

Who is funding the study?
Scottish Orthopaedic Research Trust - into trauma (SORT-it) (UK)

Who is the main contact?
Mr Tim White, tim.white@nhslothian.scot.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
88616

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 88616

Study information

Scientific Title

A prospective, randomised, controlled, multicentre, international trial comparing the fibular nail with open reduction and internal fixation for unstable ankle fractures in younger patients

Study objectives
There is no difference in outcome, as measured by Olerud and Mollander Ankle Score at 1 year, between standard open reduction and internal fixation, and fibular nailing, of unstable ankle fractures. This is an extension of a study examining outcomes using the same procedure in elderly patients only (see https://pubmed.ncbi.nlm.nih.gov/27587528/).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Initial study in elderly subjects approved 07/04/2005, Lothian Local Research Ethics Committee 02 (Deaconess House, 148 Pleasance, Edinburgh, EH8 9RS; +44 (0)131 536 9000; no email), ref: 05/S1102/02
2. Amended 07/11/2006, Lothian Local Research Ethics Committee 02 (Deaconess House, 148 Pleasance, Edinburgh, EH8 9RS; +44 (0)131 536 9000; lyndsay.baird@lhb.scot.nhs.uk), ref: 05 /S1102/02
3. Amended to enable recruitment of younger participants 04/03/2010, NHS Lothian R&D Office (Room E1.12, Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh, EH16 4TJ; +44 (0)131 242 3330; R&DOffice@luht.scot.nhs.uk), ref: 05/S1102/02, 2010/R/OP/01
4. Approved, Danish Ethics Committee, ref: H-4-2011-141

Study design
Randomized controlled two-centre clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Surgical stabilisation of ankle fractures

Interventions
Participants were randomly allocated to the control or intervention arms using sealed opaque envelope allocation with a ratio of 1:1 in batches of 20.

Control: Open reduction and internal fixation was performed in the standard manner with plates and screws.

Intervention:Fibular nailing was performed according to the manufacturer’s instructions and the investigators' previously published technique (https://www.ncbi.nlm.nih.gov/pubmed/22844054).

Duration of treatment: Surgical procedure performed within a week of injury and surgery lasts around 1 h. Moon-boot orthosis worn for 6 weeks.

Follow-up: Clinical, functional and radiological assessments were carried out at 6 weeks, 3 months, 6 months, 1 year and 2 years post-randomisation. Complications and the need for further surgery was recorded at each visit. Complications were defined as superficial or deep wound infections, loss of fracture reduction, symptomatic metalwork requiring removal, onset of neurological symptoms and/or signs following surgery, and further surgery for any cause. Superficial infections were defined as an infection that resolved with antibiotics and required no surgical intervention. Deep infections were defined as requiring a return to theatre for surgical debridement with or without subsequent removal of metalwork. Late removal of symptomatic metalwork was performed for prominence, pain and discomfort at the patient’s request only.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Acumed fibular nail

Primary outcome measure
Ankle symptoms after ankle fracture assessed using the Olerud-Molander Ankle Score core (OMAS) at 1 year

Secondary outcome measures
Complications assessed by follow-up examination at 6 weeks, 3 months, 6 months, 1 year and 2 years post-randomisation

Overall study start date
04/05/2010

Completion date
10/03/2015

Eligibility

Key inclusion criteria
1. Aged ≥18 to <65 years
2. Unstable fracture of the ankle
3. Within 2 weeks of fracture
4. No ipsilateral injury to the lower limb

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
125

Key exclusion criteria
1. Patients unable to give informed consent or those with cognitive impairment
2. Bilateral injuries or ipsilateral injury to the lower limb
3. Pilon fractures
4. Patients unable to comply with follow-up

Date of first enrolment
18/09/2011

Date of final enrolment
24/02/2013

Locations

Countries of recruitment
Denmark

Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh
Little France
Edinburgh
United Kingdom
EH16 4SU

Study participating centre
Hvidovre University Hospital
Copenhagen
Denmark
2650

Sponsor information

Organisation
NHS Lothian

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Sponsor type
University/education

Website
http://www.nhslothian.scot.nhs.uk/Pages/default.aspx

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Research organisation

Funder Name
Scottish Orthopaedic Research Trust into Trauma (SORT-it)

Results and Publications

Publication and dissemination plan
For publication in a prominent orthopaedic journal.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to conditions pertaining at the ethical approval stage.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v4	17/08/2009	15/05/2020	No	Yes