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UK heel fracture trial: surgical treatment versus non-operative care

Submission date	Recruitment status	[X] Prospectively registered
07/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/07/2014	Musculoskeletal Diseases	

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
15964

Study information

Scientific Title
Improved functional outcome in heel fracture with surgical treatment versus non-operative care: a randomised controlled trial

Study objectives
Surgical treatment leads to improved functional outcome compared with non-operative care.

Please note that as of 09/02/2009 the trial start and end dates of this record were updated. The initial dates at the time of registration were:
Initial anticipated start date: 01/01/2006
initial anticipated end date: 30/06/2010

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire REC A, 24/05/2006, ref: 06/Q1604/58

Study design
Observer blind randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Calcaneal fracture

Interventions
Intervention: open reduction and internal fixation by extensile lateral approach
Control: non-surgical treatment with elevation and ice followed by spintage and early mobilisation

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The Kerr Calcaneal Fracture Score (a validated, reliable, patient-derived outcome instrument for pain and function following calcaneal fracture, accepted by surgeons working in the area)

Secondary outcome measures
Amended as of 09/02/2009:
Point four has been amended as follows:
4. Gait and foot pressure analysis using F-Scan for gait analysis. This is an in shoe pressure system which also enables objective assessment of various parameters of gait.

Initial information at time of registration:
1. Complications, including wound dehiscence, infection, mal-union, non-union and radiographic arthritis
2. General health using the SF-36 questionnaire
3. American Orthopaedic Foot and Ankle Society Hind Foot Score
4. Gait and foot pressure analysis using GAITRite (a simple portable pressure sensitive mat connected to a laptop computer that enables objective assessment of various parameters of gait including walking speed, step length, and dynamic contact pressures)
5. Health status using EQ-5D
6. Resource use will be monitored for the economic analysis. National Health Service (NHS) costs will be collated for each trial arm. Cost-consequences will be monitored via short questionnaires. In addition, average time off work or reduced working hours attributed to the condition in both groups will be recorded.

Overall study start date
01/06/2006

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Closed displaced intra-articular fractures of the calcaneus
2. Aged over 18 years, no upper age limit, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150; 75 in each group

Key exclusion criteria
Amended as of 09/02/2009:
1. Calcaneal fracture with severe deformity resulting in fibula impingement
2. Previous calcaneal abnormality (infection, tumour or deformity)
3. Other serious injuries to either lower limb that would interfere with rehabilitation of the index calcaneal fracture
4. Peripheral vascular disease (defined as having been investigated or treated for poor lower limb circulation)
5. Other contra-indication to surgery, defined as:
5.1. Severe cardiac impairment, e.g. heart or valve replacement, arrhythmia, previous myocardial infarction
5.2. Severe respiratory impairment, e.g. chronic obstructive pulmonary disease, asthma that has required hospital admission
5.3. Any other systemic medical condition that would produce a specific contraindication to a general anaesthetic
6. Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as dementia or intravenous drug abuse

Initial information at time of registration:
1. Diabetes
2. Peripheral vascular disease, or other local or systemic contra-indication to surgery
3. Injury to the ipsilateral leg
4. Very severe deformity with the lateral wall of the calcaneus impinging upon the fibula

Date of first enrolment
01/06/2006

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Medical School
Coventry
United Kingdom
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Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK) (ref: 15964)

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	24/07/2014		Yes	No