Musculoskeletal Diseases

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

Submission date 07/02/2006	Recruitment status No longer recruiting		
Registration date 22/02/2006	Overall study status Completed		
Last Edited	Condition category		

[X] 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

28/07/2014

Contact name Prof Damian Griffin

Contact details

Warwick Medical School Clinical Sciences Building Research Wing Clifford Bridge Road Coventry United Kingdom CV2 2DX +44 (0)2476 968618 damian.griffin@warwick.ac.uk

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 CV2 2DX

Sponsor information

Organisation University Hospitals Coventry and Warwickshire NHS Trust (UK)

Sponsor details

University Hospital Walsgrave Coventry England United Kingdom CV2 2DX +44 (0)2476 602020 info@uhcw.nhs.uk

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