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A trial comparing weight bearing to non-weight bearing following ankle fracture fixation

Submission date	Recruitment status
30/07/2010	Stopped
Registration date	**Overall study status**
27/10/2010	Stopped
Last Edited	**Condition category**
08/02/2016	Injury, Occupational Diseases, Poisoning

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

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
N/A

Study information

Scientific Title

A randomised controlled trial to compare the functional outcomes of two weight bearing protocols following open reduction and internal fixation of ankle fractures

Study objectives
As well as developing the evidence-base and addressing this limitation identified by the systematic review, this proposed study has considerable clinical implications. Due to the frequency of this injury, the management of ankle fractures is important in the bed-management of orthopaedic wards and outpatient clinics in the National Health Service (NHS). Furthermore, surgeons at present commonly restrict their patients to non-weight bearing (hopping) for the initial six post-operative weeks. Some patients, particularly the elderly and weak find this difficult, and may be unable to walk during this period. As a result, these patients have a reduced level of independence, and may require hospital, or care home support during this period until they can begin weight bearing after fracture union. This has considerable cost implications, as well as affecting quality of life and independence. Younger patients in full time employment may also find work difficult with strict non-weight bearing protocols.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-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
Closed ankle fractures

Interventions
Both the delayed and early weight bearing groups will have a backslab applied at the time of surgery. At 2 weeks this will be converted to a full non weight bearing cast in the delayed weight bearing group and an aircast boot (full weight bearing) in the early weight bearing group. At 6 weeks both groups will be allowed to fully bear weight free of cast or boot.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Olerud and Molander Subjective Ankle Score: This was chosen as the primary outcome measure since our research question asks that we assess patient's function primarily, which this outcome measure satisfies. Furthermore, previous authors have used this outcome measure in their investigations on ankle fracture management, and therefore, by using this outcome measure, we would be able to compare our findings to their results. Finally, although the reliability and validity of this tool has not been formally assessed for ankle fracture populations, the literature suggests that such a procedure has not been assessed with any outcome measure, and due to the other two factors, it was deemed that this would be the most appropriate outcome measure. Measured at 6 weeks, 3 months, 6 months, 1 year.

Secondary outcome measures
1. EQ-5D, assessed in the clinic setting. Although this measure is frequently assessed as a postal questionnaire, it will be assessed in the clinic to increase the response rate. Measured at 6 weeks, 3 months, 1 year; range of motion at 6 weeks
2. Range of ankle plantar flexion and dorsiflexion of both the injured and un-injured ankle. This will be assessed using goniometry and the bony landmarks of the head of the fifth metatarsal, and the fibula head
3. Patient reported outcome measures will also be a requirement within the UK National Health Service
4. Any post-operative complications such as infection, mal-union, implant loosening or breakage, deep vein thrombosis (DVT), measured at 6 weeks
5. Total time lost from work by asking each patient how long they required off work if applicable
6. Duration of in-patient hospital stay by reviewing the medical notes
7. Duration of physiotherapy rehabilitation by reviewing the physiotherapy notes, assessed at one year
8. Finally anatomical reduction and time to fracture union, assessed by an orthopaedic surgeon using clinical and radiographic examination. The latter assessment will be determined by satisfying the following criteria:
8.1. No bony tenderness on palpation around the fracture site
8.2. Pain-free weight bearing (determined as when the patient can stand solely on the injured leg reportedly pain-free for a total of 10 seconds)
8.3. Bridging callus on at least two cortices (orthogonal) on plain radiographs
Measured at 2 weeks

Overall study start date
01/01/2011

Completion date
31/12/2013

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Patients with ankle fractures admitted for an open reduction internal fixation (ORIF) by the Trauma and Orthopaedic Department at St George's Hospital and St Thomas' Hospital
2. Radiological evidence of a fracture of the ankle requiring fixation which occurs alone (AO classification: 44-A1.2, 44-A1.3, 44-A2.1, 44-A2.2, 44-A2.3, 44.A3.1, 44-A3.2, 44-A3.3, 44-B1.1, 44-B1.2, 44-B1.3, 44.B2.1, 44-B2.2, 44-B2.3, 44-B3.1, 44-B3.2, 44-B3.3, 44-C1.1, 44-C1.2, 44-C1.3, 44.C2.1, 44-C2.2, 44-C2.3, 44-C3.1, 44-C3.2, 44-C3.3 ; Arbeitsgemeinschaft für Osteosynthesefragen /Orthopedic Trauma Association [AO/ATO] Classification, 2007)
3. Female and male subjects greater than or equal to 18 to 70 years
4. Body mass index (BMI) 16 - 33 kg/m^2 (minimum body weight 50 kg, maximum 140 kg)
5. Glasgow coma score (GCS) 15
6. Signed Informed Consent Form. The patient has to be able to give consent personally

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
76

Key exclusion criteria
1. Inability to undertake assessment and treatment procedures
2. Contralateral lower limb injury
3. Inability to non-weight bear initially if allocated to non-weight bearing group
4. Unstable or relative stability ORIF due to surgical difficulty and fracture configuration or poor bone stock (e.g. osteoporosis) as determined by unstable valgus/varus testing on image intensifier in theatre and post-operative notes
5. Rupture to the syndesmosis
6. Previous ankle fracture
7. Anderson and Gustilo Grade II and III open fractures
8. Fixation requiring bone grafting
9. Active or past history of malignant tumour
10. Evidence of systemic or localised infection at time of surgery
11. Evidence of immunosuppression
12. Diagnosis of diabetes mellitus (Type I or Type II)
13. Gross osteoarthitic changes of the ankle joint (Grade 3 or above)
14. Previous surgical intervention to the operated ankle
15. Inability to attend out-patient physiotherapy appointments
16. Inability to independently mobilise with or without walking aids
17. Unwillingness to participate

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's Hospital
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United Kingdom
SW17 0QT

Sponsor information

Organisation
St George's Healthcare NHS Trust

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Charity

Funder Name
St George's Hospital Orthopaedic Research Fund

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