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

Submission date	Recruitment status	[X] Prospectively registered
30/07/2010	Stopped	[_] Protocol
Registration date	Overall study status	Statistical analysis plan
27/10/2010	Stopped	[_] Results
Last Edited	Condition category	Individual participant data
08/02/2016	Injury, Occupational Diseases, Poisoning	[_] Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Miss Caroline Hing

Contact details

St George's Hospital Tooting London United Kingdom SW17 0QT

## 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** London United Kingdom SW17 0QT

## Sponsor information

**Organisation** St George's Healthcare NHS Trust

#### Sponsor details

c/o Philip Mitchell St George's Hospital Blackshaw Road Tooting London England United Kingdom SW17 0QT +44 (0)20 8672 1255 Philip.mitchell@stgeorges.nhs.uk

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