

AIR: Ankle injury rehabilitation

Submission date 05/11/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/02/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Ankle fractures are a very common injury in which one or more of the bones which make up the ankle joint are broken. It can be extremely painful, making it difficult or even impossible to walk. In some cases, when the fracture is particularly serious, the ankle may need to be “surgically fixed”. This is an operation in which the broken pieces of bone are lined up, and held in place with wires, screws or metal plates. It is particularly effective because it ensures that the bones heal in the correct position, which can avoid problems in later life such as arthritis (long-term swelling, stiffness and pain in the joints). Traditionally, after this procedure the patient is required to wear a plaster cast for several weeks to ensure that the ankle bones do not move around while they are healing (immobilisation). Studies have shown however, that complete immobilisation of the ankle can cause deep vein thrombosis (a blood clot in a deep vein), as well as difficulty returning to normal activity when the cast comes off. A possible alternative could be providing the patient with a removable functional brace. This does not provide as much support as a conventional cast, but it does allow removable so that the ankle can be gently exercised which could help to recover the ankle’s range of movement. The aim of this study is to look at the effects of functional bracing and plaster casts on ankle healing following surgical fixation.

Who can participate?

Patients over 16 years of age with a fractured ankle that requires surgical fixation.

What does the study involve?

All participants undergo surgical fixation of their ankle fracture and are given standard care for 10 days until their stitches are removed. They are then randomly allocated to one of two groups. Participants in the first group are given a removable functional brace to wear for a further four weeks. They are encouraged to remove the brace three times a day and complete exercises, designed to improve the range of movement in their ankle. Participants in the second group have a standard cast fitted (made of either plaster of Paris or fiberglass). This cast remains in place for four weeks and cannot be removed. Participants in both groups complete a number of questionnaires at the start of the study, and then at 6 weeks, 3 months and 6 months, in order to measure how well they are recovering from their ankle fracture.

What are the possible benefits and risks of participating?

There are no direct benefits or risks of the trial to participants. It is not known which of these treatments gives the best results; both treatments are already available and used widely within

the NHS. Both treatments are widely used for people with this injury. This study may improve the treatment of ankle fractures in the future there is no specific advantage to you for taking part in the study.

Where is the study run from?
University Hospitals Coventry (UK)

When is the study starting and how long is it expected to run for?
November 2015 to August 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Catherine Lawrence

Study website
<http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/musculoskeletalpain/air>

Contact information

Type(s)
Public

Contact name
Dr Joanne O'Beirne-Elliman

Contact details
Warwick Clinical Trials Unit
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Gibbet Hill Road
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19853

Study information

Scientific Title

Ankle Injury Rehabilitation: Is it feasible to conduct a randomised controlled trial to assess the difference between functional bracing versus plaster cast for the treatment of fixed ankle fractures (AIR)

Acronym

AIR

Study objectives

This study aims to determine whether it is feasible to conduct a full randomised controlled trial to assess the difference between functional bracing versus plaster cast for the treatment of fixed ankle fractures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First Medical Research Ethics Committee, 21/10/2015, ref: 15/WM/0340

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

All participants who require ankle fixation will have this performed according to the preferred technique of the operating surgeon. The details of the surgery will be left to the discretion of the surgeon to ensure that the results of the trial can be generalised. However, a copy of the 'operating record' will form part of the trial dataset, including the grade and experience of the surgeon. All participants will then be placed in a back slab until the stitches are removed approximately ten days post operatively.

All participants not receiving surgery will be approached to take part in the trial on first presentation to the trauma team fracture clinic.

Control Group - Standard Plaster Cast:

All participants in the control arm will be immobilised with a plaster cast for a further four weeks as per standard practice; the cast may be plaster of paris or fibreglass.

Intervention Group – Functional Bracing:

All participants in the intervention arm will be fitted with a removable functional brace for a further four weeks. Throughout this period participants will be encouraged to remove their functional brace to complete active unloaded ankle range of movement exercises three times per day, completing ten repetitions on each occasion.

The effect of the injury and the patients' recovery will be assessed using a questionnaire, with follow up at six weeks, three and six months.

Intervention Type

Other

Primary outcome measure

Health outcomes are determined using the Manchester–Oxford Foot Questionnaire (MOXFQ) at baseline and 6 months.

Secondary outcome measures

1. Complications are recorded using Complications CRF (created in house, not a validated questionnaire) at baseline, post-treatment, 6 weeks, 3 months and 6 months
2. Health outcomes measured using the EQ-5D questionnaire, the Manchester–Oxford Foot Questionnaire (MOXFQ) and the Olerud-Molander Ankle Score (OMAS) at baseline, post-treatment, 6 weeks, 3 months and 6 months
3. Healing is determined by viewing copies of routine pre- and post-operative x-rays taken at baseline, 6 weeks and 6 months

Overall study start date

01/07/2015

Completion date

31/05/2017

Eligibility

Key inclusion criteria

1. Aged 16 years or over
2. Ankle fracture for which the treating clinician would consider plaster cast a reasonable management option

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 50; UK Sample Size: 50; Description: As this is a feasibility study a formal power analysis for the sample size will not be undertaken, as the study is not designed to test a specific null hypothesis, and infer significance to any observed treatment differences. Instead we adopt a more informal approach, based on the aims of (i) assessing the distributional properties of the MOXFQ (specifically the variance) and (ii) assessing the likely participation rate (the proportion of eligible patients who are likely to agree to participate)

Total final enrolment

50

Key exclusion criteria

1. Lack of capacity to consent
2. Unable to walk prior to injury
3. Previous ankle fracture randomisation in the present trial
4. Open fracture
5. Pathological fractures, i.e. known metastatic disease
6. Evidence that the patient would be unable to adhere to trial procedures or complete postal questionnaires
7. Any other lower limb injury (including bilateral ankle fractures and syndesmosis injury requiring surgery, contraindication to cast application) that will affect the primary outcome measure
8. In the opinion of the surgeon the patient would require Close Contact Casting

Date of first enrolment

10/11/2015

Date of final enrolment

19/09/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University Hospitals Coventry

Medical Oncology

Clinical Sciences Research Unit

Clinical Sciences Building

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

University of Warwick

Sponsor details

University House
Kirby Corner Road
Coventry
England
United Kingdom
CV4 8DS

Sponsor type

Hospital/treatment centre

Website

<http://www2.warwick.ac.uk/>

ROR

<https://ror.org/01a77tt86>

Organisation

University Hospitals Coventry & Warwickshire NHS Trust

Sponsor details

Medical Oncology Clinical Sciences Research Unit
Clinical Sciences Building
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

31/05/2018

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	17/11/2015	15/11/2016	No	Yes
Protocol article	protocol	01/03/2017		Yes	No
Results article	results	17/04/2019	25/02/2021	Yes	No
HRA research summary			28/06/2023	No	No