

A clinical trial comparing the effectiveness of a plaster cast to a functional brace in the treatment of adults with ankle fractures

Submission date 17/07/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/07/2017	Overall study status Completed	<input checked="" type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/09/2023	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Ankle fractures represent 9% of the trauma workload and demand is increasing. This number is expected to grow due to an increase in older adults who are remaining active. The frequency of this injury is an increasing burden on the NHS year on year. The short-term impact of this injury results in physical impairments of pain, stiffness, weakness and swelling. The longer-term impact results in prolonged time off work, development of posttraumatic arthritis and psychological consequences of depression and anxiety. Ankle fractures that occur below the level of the syndesmosis (the movable joint that connects the two lower leg bones) are considered 'stable' and are usually treated with functional braces. All other ankle fractures are less stable, with some requiring a surgery called open reduction and internal fixation (ORIF) with the aim of restoring stability. Regardless of the decision to operate or not, the immediate management has traditionally been plaster cast for several weeks, while the bone heals. A cast provides maximum support; however, there are potential problems. Firstly, there is the immediate impact on mobility (ability to move) for a period of around six weeks. Secondly, there are the risks associated with not moving the ankle for a long time such as muscle atrophy (wasting), deep vein thrombosis (blood clots forming in a deep vein) and joint stiffness. Finally, there are the long-term consequences, which include prolonged gait (way of walking) abnormalities, persistent calf muscle weakness and an inability to return to previous activity levels. Alternative functional bracing may potentially address these issues. However, it does not provide the same degree of support to the healing bones. The aim of this study is to evaluate if there is a difference in ankle function and symptoms between a plaster cast and a functional brace.

Who can participate?

Adults aged 18 and older who have an ankle fracture that requires a cast and is within three weeks of surgery or injury.

What does the study involve?

Participants are allocated to one of two groups. Those in the first group receive the functional brace which is worn for three to eight weeks depending on their clinician's advice. They receive an exercise sheet that outlines two simple exercises to help maintain and improve the

movement in their ankle joint. This is done as often as the pain allows. Those in the second group receive a plaster cast which is worn for three to eight weeks depending on their clinician's advice. Participants are followed up for two years and complete surveys via the post and receive their routine follow up by their treating clinician.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

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

When is the study starting and how long is it expected to run for?
January 2017 to December 2021

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

Who is the main contact?
Dr Rebecca Mckeown
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Study website
<http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/airmain>

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

35014

Study information

Scientific Title

Ankle Injury Rehabilitation - A multi-centre randomised controlled trial to assess the difference between plaster cast and functional bracing in the management of ankle fractures

Acronym

AIR

Study objectives

The aim of this study is to see if there is a difference in the Olerud Molander Ankle Score at 4 months post randomisation between plaster cast and functional bracing for the treatment of ankle fractures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee – West Midlands, Edgbaston, 04/07/2017, ref: 17/LO/1015

Study design

Randomised; Interventional; Design type: Treatment, Complex Intervention, Physical, Rehabilitation

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

Ankle fracture

Interventions

All adults with a fractured ankle under the care of a clinician at any of the named recruiting sites are potentially eligible. New patients with an ankle fracture are reviewed each day by the trauma team. Participants are randomised to either receiving either the functional brace or the plaster cast. This process of randomisation is done via a computer generated sequence to determine the treatment to be given.

The plaster cast or functional brace is usually worn from three to eight weeks, which is decided by the treating clinician. The clinician also decides how much weight can be put on the healing ankle.

Participants who receive the functional brace are also be given an exercise sheet, outlining two very simple exercises to maintain and improve the movement in the ankle joint. It is recommended these are completed little and often, as pain allows.

Participants are followed up in this study for a duration of two years and all trial follow up is completed by post. Participants will receive routine follow up by their treating clinician.

Intervention Type

Other

Phase

Phase III

Primary outcome measure

Symptom evaluation is measured using Olerud Molander Ankle Score questionnaire (this will be collected using patient questionnaires sent via post) at 4 months

Secondary outcome measures

1. Symptom evaluation is measured using Olerud Molander Ankle Score questionnaire at six weeks, 10 weeks, six months and 24 months
2. Surgical outcomes are measured using the Manchester-Oxford Foot and Ankle Questionnaire at four months
3. Health status is measured using EuroQol five dimensions questionnaire (EQ-5D) at "6 weeks, 10 weeks, 16 weeks, 24 weeks, 12 months, 18 months and 24 months.
4. Disability is measured using the disability rating index at "6 weeks, 10 weeks, 16 weeks, 24 weeks, 12 months, 18 months and 24 months
5. Cost is measured using a patient reported questionnaire at "6 weeks, 10 weeks, 16 weeks, 24

weeks, 12 months, 18 months and 24 months

6. Complication rate is measured using a patient reported questionnaire at "6 weeks, 10 weeks, 16 weeks, 24 weeks, 12 months, 18 months and 24 months

Overall study start date

01/01/2017

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Provision of written informed consent
2. Aged 18 years or over
3. A closed ankle fracture for which the treating clinician would consider plaster cast a reasonable management option
4. Within 3 weeks of operative treatment or injury if non-operatively managed

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: a minimum of 478; UK Sample Size: a minimum of 478

Total final enrolment

671

Key exclusion criteria

1. Ankle fracture secondary to known metastatic disease
2. Complex intra-articular fracture (e.g. Pilon fracture)
3. In the opinion of the surgeon the patient would require manipulation and close contact casting
4. In the opinion of the surgeon the patient would require manipulation and moulded cast
5. Wound complications following surgical management contraindicating Functional brace intervention
6. Previous ankle fracture randomised in the present trial
7. Evidence that the patient would be unable to adhere to trial procedures or complete postal questionnaires
8. Known pre-existing neuropathic joint disease contraindicating functional brace intervention

Date of first enrolment

01/10/2017

Date of final enrolment

30/09/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals Coventry and Warwickshire

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

Sponsor information

Organisation

University of Warwick

Sponsor details

Sponsorship Office

Gibbett Hill Road

Coventry

England

United Kingdom

CV4 7AL

Sponsor type

University/education

ROR

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

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 high-impact peer reviewed journal no later than 12 months after the end of the follow up period.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/12/2018	04/11/2019	Yes	No
Results article		05/07/2021	07/07/2021	Yes	No
Results article		06/07/2021	30/07/2021	Yes	No
Other publications	Qualitative pre-results	04/02/2020	06/09/2023	Yes	No