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AIR: Ankle injury rehabilitation

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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

Contact information

Type(s)
Public

Contact name
Dr Joanne O'Beirne-Elliman

Contact details
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

ROR
https://ror.org/01a77tt86

Organisation
University Hospitals Coventry & Warwickshire NHS Trust

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

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?
Results article	results	17/04/2019	25/02/2021	Yes	No
Protocol article	protocol	01/03/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	17/11/2015	15/11/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes