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Does early mobilisation after ankle fracture surgery enhance recovery?

Submission date	**Recruitment status**	[X] Prospectively registered
08/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
08/01/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/01/2024	Surgery	[_] Record updated in last year

Plain English Summary

Background and study aims

Ankle fractures are common and many require surgery. After surgery, patients are managed in many different ways depending on their age, physical ability, fracture type, bone quality and surgeon. However, guidelines and evidence suggest that being able to actively move the ankle a couple of weeks after surgery in a removable boot might be beneficial to the patient. The two methods being compared are plaster cast and an Aircast® boot. Managing an ankle fracture with a plaster cast means that patients keep their injured ankle relatively still (immobilised) whilst managing an ankle fracture with an Aircast® boot means that patients can move their injured ankle quite soon after surgery – this is called early mobilisation. The findings of this study will be used to determine which treatment is best and which, if any, can be recommended as standard care for patients who fracture their ankles and need surgery.

Who can participate?

Adults that have recently had surgery for an ankle fracture.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are given a plaster cast. Those in group 2 are given a removable support boot. All participants then attend a clinic appointment 4 weeks later (6 weeks post-surgery) and assessments performed. Participants are asked to complete questionnaires at 5 weeks (7 weeks post- surgery) and (12 weeks post-surgery). Up to twenty patients are also asked to take part in telephone interviews to describe their experiences of their treatment. These data is compared between the two groups in order to evaluate which treatment is best in terms of function, quality of life, psychological, social, economic impact and patient experience as well as costs and benefits to the National Health Service, patients and society.

What are the possible benefits and risks of participating?

Whilst there are no immediate benefits for those people participating in the project, it is hoped that their participation will mean those in the future who experience a similar injury will receive the best/most appropriate treatment for their injury and will make the best use of NHS resources.

Where is the study run from?
Poole Hospital NHS Foundation Trust (lead site) and other NHS hospitals in the South East of England (UK)

When is the study starting and how long is it expected to run for?
February 2015 to April 2019

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

Who is the main contact?
Mr Lee Tbaily

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18022

Study information

Scientific Title
Does early mobilisation after Ankle fracture surgery enhance Recovery? A pragmatic multi-centre randomised controlled Trial with qualitative component and health economic analysis comparing the use of plaster versus Aircast® boot.

Acronym
ART V1.0

Study hypothesis
The aim of the study is to evaluate the relative effectiveness and cost-effectiveness of two methods of post-operative ankle fracture management (plaster versus Aircast® boot with range of movement) and to provide evidence-based recommendations for best care in clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central – Hampshire A, 22/12/2014, ref: 14/SC/1409

Study design
Randomized 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

Condition
Topic: Musculoskeletal, Surgery; Subtopic: Musculoskeletal (all Subtopics), Surgery; Disease: Musculoskeletal, Surgery

Interventions
Current Interventions as of 06/12/2017:
1. Removable support boot: Removable boot with range of movement for four weeks
2. Plaster Cast: Plaster below knee i.e. immobilised for four weeks

Previous Interventions:
1. Aircast® boot: Aircast® boot with range of movement for four weeks
2. Plaster Cast: Plaster below knee i.e. immobilised for four weeks

Intervention Type
Procedure/Surgery

Primary outcome measure
Olerud and Molander Ankle Score; Timepoint(s): Five weeks post randomisation

Secondary outcome measures

1. Ankle functional data (range of movement, weight-bearing)
2. Standardised measure of general quality of life (EQ-5D-5L)
3. Healing status
4. Complications
5. Return to Usual Activities

Overall study start date
01/03/2015

Overall study end date
30/04/2019

Eligibility

Participant inclusion criteria
1. Received surgery for fixation of unstable ankle fracture
2. Provision of informed consent to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 246; UK Sample Size: 246

Total final enrolment
262

Participant exclusion criteria
1. Under 16 years old (skeletally immature)
2. Poor skin condition at operation site
3. Serious concomitant disease (e.g. stroke, osteoporosis, arthritis)
4. Diabetic neuropathy/other sensory neuropathy (lack of sensation)
5. Non-ambulatory prior to injury
6. Active leg ulceration
7. Patients who are unable to understand the study information or unable to complete the outcome questionnaires
8. Surgeon concerned about quality of fixation/integrity of wound
9. Fracture requiring further stabilisation in/around the ankle (e.g. syndesmosis).
10. Open ankle fracture (bone broken through skin)
11. Participant is a participant in other concurrent interventional research which may over-burden the participant or confound data collection
12. Concomitant injuries which will have a confounding effect on rehabilitation in the opinion of the investigator

Recruitment start date
01/08/2015

Recruitment end date
31/08/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Poole Hospital NHS Foundation Trust
Dorset Research and Development Support Unit
Cornelia House
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough

United Kingdom
PE3 9GZ

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Yeovil District Hospital
Yeovil District Hospital
Higher Kingston
Yeovil

United Kingdom
BA21 4AT

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust

Sponsor details
Dorset Research and Development Support Unit
Cornelia House
Longfleet Road
Poole
England
United Kingdom
BH15 2JB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03kdm3q80

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
A number of scientific papers will be produced from the collated anonymised study data. Results will be published in peer reviewed journals aimed at both surgeons and physiotherapists (e.g. Annals of the Royal College of Surgeons, Journal of Bone and Joint Surgery and Physiotherapy. Papers will include messages about functional, socio-economic and psychological outcomes as well as the publication of the protocol. Results will also be published in the Health Service Journal, to authors of the Cochane review, and findings will be disseminated at conferences and via oral presentations at local, national and international trauma/orthopaedic and physiotherapy meetings. Participants and the general public will also be informed via via flyers, posters, Bournemouth University Clinical Research Unit website, Bournemouth University Research Blog, Twitter, podcast, press releases to the media.

Intention to publish date
30/04/2024

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 file	version 1.6	05/03/2018	14/03/2023	No	No
Statistical Analysis Plan	version 1.1		14/03/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications	Cost-effectiveness analysis and qualitative findings	11/01/2024	15/01/2024	Yes	No