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Early motion and directed exercise (EMADE) in ankle fracture fixation

Submission date
13/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
18/02/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ankle fractures are very common, comprising up to 20% of all leg fractures. The best type and timing of rehabilitation for this condition remains unclear. For those who need to have surgery to fix their ankle fracture it is normal for them to remain in a leg cast and not put the foot to the floor for 6-weeks. However, early exercise, outside of a cast, could be a viable option. The study team has created an Early Motion And Directed Exercise (EMADE) rehabilitation programme, which is designed to be used from the second to the sixth week after surgery. The aim of this study is to find out whether starting physiotherapy early using the EMADE programme can help patients who have had surgery to fix ankle factors recover more quickly and completely.

Who can participate?
Adults who have a fractured ankle which is being treated by surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are fitted with a light-weight below knee cast and remain non-weightbearing while walking until the six-week orthopaedic clinic review. Those in the second group are fitted with a removable cast that is retained with Velcro straps. They are also non-weightbearing during gait until the six-week orthopaedic clinic review. These participants take their cast off to conduct exercises several times per day at home. These exercises include bending the ankle towards them and pointing the ankle and toes down, and later strengthen with elastic exercise bands. During weekly one-to-one physiotherapy sessions (three, four and five weeks after surgery) the frequency and intensity are progressed on an individual basis. Hands-on treatments and education on the condition and responses to exercise are also provided. From the six-week orthopaedic review, it is common for the cast to be removed and if the X-ray is satisfactory, participants in both groups can then start taking weight on the ankle while walking. Participants complete questionnaires about their symptoms and function at the start of the study and at six, 12, 24 and 52 weeks following their surgery.

What are the possible benefits and risks of participating?
There is no guarantee of direct benefits however the information gained may contribute to improving treatment for ankle fractures in the future. There are no notable risks involved with participating.

Where is the study run from?
Queen's Medical Centre (UK)

When is the study starting and how long is it expected to run for?
November 2011 to December 2018

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
1. Miss Jess Nightingale (public)
jessica.nightingale@nuh.nhs.uk
2. Mr Benhamin Ollivere (scientific)
Benjamin.Ollivere@nottingham.ac.uk

Study website
http://www.sportsarthritisresearchuk.org/research-projects/project-list/emade.aspx

Contact information

Type(s)
Public

Contact name
Ms Jess Nightingale

Contact details
Trauma and Orthopaedics
C Floor, West Block, QMC
Nottingham University Hospitals
Derby Road
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 924 9924 (ext. 67502)
jessica.nightingale@nuh.nhs.uk

Type(s)
Scientific

Contact name
Mr Benjamin Ollivere

ORCID ID
http://orcid.org/0000-0002-1410-1756

Contact details
Academic Orthopaedics, Trauma and Sports Medicine
University of Nottingham
Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 82 31115
Benjamin.Ollivere@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18892

Study information

Scientific Title
Early motion and directed exercise (EMADE) post ankle fracture fixation: a pragmatic randomised controlled trial

Acronym
EMADE

Study objectives
Early motion and directed exercise (EMADE) physiotherapy will perform better than usual care at three months following operative fixation of a Weber B fracture as measured by the Oleurd and Molander Score (OMAS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands – Nottingham 2, 04/11/2014, ref: 14/EM/1213

Study design
Randomised; Interventional; Design type: Treatment, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Injuries and emergencies, Primary sub-specialty: Injuries and emergencies

Interventions
Participants receive identical care pre-operatively and in the first two post-operative weeks consisting of admission to hospital, consultant supervised surgery including management on a standard care pathway. Participants are discharged home in a plaster cast and reviewed two weeks following surgery. All participants undergo x-ray and wound inspection following plaster removal at the two week review. All participants are non-weightbearing throughout the study until the six week point.

Participants in the intervention group at two weeks fitted with a removable cast (3M Delta-cast soft cast, with an integrated focussed rigid back-slab casting and Velcro retaining straps). At the two-week review a focussed physiotherapy exercise programme commences up to six times a day. The range-of-motion and strengthening home exercise programme is taught during weekly face to face sessions (weeks three, four and five post-surgery) and progressed as appropriate. To encourage compliance with the EMADE home exercise programme, written and pictorial instructions are provided. During sessions manual therapy and education is provided as per protocol.

Participants in the usual care group are treated in a plaster until the six week point.

From the six-week review all study participants receive the same standard care. This includes removal of casts and if appropriate on X-ray review, commencement of weight bearing as tolerated, and physiotherapy as required. Protocol deviations, as per standard care, are based on individual clinical decision, for example removal of metal work, including syndesmosis screws.

Intervention Type
Other

Primary outcome measure
Symptoms and function, are measured by the Olerud and Molander ankle score (OMAS) patient reported outcome measure (PROM), recorded at 2 and 6-weeks post-surgery, as baseline and end-of-intervention respectively and at 12 (Primary timepoint) 24 and 52-weeks post-surgery.

Secondary outcome measures
1. Symptoms and function, are measured using the Ankle Fracture Outcome of Rehabilitation Measure (A-FORM) PROM and use of walking aids at; 2, 6, 12, 24 and 52-weeks post-surgery
2. Generic quality of life is measurers using the EuroQoL EQ-5D-5L and level of activity PROMs at; 2, 6, 12, 24 and 52-weeks post-surgery
3. Health and social economic impact, are measured by ability and time to return to work and return to driving (where applicable), ankle related hospital attendance, quality adjusted life

years (derived from the EQ-5D-5L), and complication rates are recorded through reviewing routine X-rays, hospital attendance and adverse events at; 2, 6, 12, 24 and 52-weeks post-surgery 4. Objective Ankle function is measured by non-weightbearing range-of-motion (dorsiflexion and plantar flexion) and tape measured ankle and calf sizes at; 2 and 6weeks post-surgery. Objective Ankle function measures are repeated with the addition of weightbearing dorsiflexion, walking speed, balance and isokinetic planter flexion strength at; 12, 24 and 52-weeks post-surgery

To mitigate against bias, participants complete the 12-, 24- and 52-week PROMs, concealed from the researchers. A third party, blinded to the intervention group inputs the data, and analysis of the PROMs is completed by a Statistician, who is also blinded to the intervention group.

Overall study start date
01/11/2011

Completion date
20/06/2019

Eligibility

Key inclusion criteria
1. Aged 18 and over
2. Independently living
3. Isolated and closed Weber B ankle fractures which are stable following internally fixation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
156

Total final enrolment
157

Key exclusion criteria
1. Inability to provide informed consent
2. Diabetes
3. Non-healing leg/foot ulcers
4. Steroid users
5. Pre-existing ankle arthritis and concurrent or history of significant ipsilateral or contralateral lower limb injury/condition e.g. contralateral leg prosthesis
6. Neurological disorders

Date of first enrolment
11/06/2015

Date of final enrolment
19/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Trauma and Orthopaedics
C Floor
West Block
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton in Ashfield
United Kingdom
NG17 4JL

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
AO Documentation and Publishing Foundation

Results and Publications

Publication and dissemination plan

Publications will include a final report and presentations at scientific conferences and meetings, with the overall results published in high-impact peer reviewed journal, approximately one year after the overall trial end date. Additional dissemination may include patient/public participation seminars and meetings, such as those organised by Arthritis Research UK.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The current 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?
Participant information sheet	version V2.1	04/11/2016	23/03/2017	No	Yes
Protocol article	protocol	31/05/2018		Yes	No
Results article		01/05/2020	18/02/2022	Yes	No
HRA research summary			28/06/2023	No	No