ISRCTN84536917 https://doi.org/10.1186/ISRCTN84536917

Supports for Ankle Fractures in Early Rehabilitation (SAFER)

Submission date	Recruitment status	[_] Prospectively registered
30/04/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/05/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2017	Surgery	

Plain English summary of protocol

Background and study aims
Patients with a broken ankle requiring surgery often have their ankle immobilised in a cast for several weeks. After the cast is removed they can start weight bearing on the ankle during walking. The main aim at this stage is to recover a quality walking pattern. Patients are often given an ankle support for the first few weeks of walking out of the cast. There are several different types of support with varied design. The supports limit different movements of the ankle but we currently do not know what effects these supports have on walking quality at this crucial early period of recovery. The aim of this study is to determine the effects of ankle supports on walking and pain 6 weeks after ankle internal fixation surgery in adults.

Who can participate?
Adults aged 18 or over who have undergone internal fixation surgery for an isolated ankle fracture.

What does the study involve?
Three different ankle supports that are currently used in clinical practice will be examined as part of this study. Walking quality in each of the supports will be evaluated by asking the participant to walk across an electronic walkway. The walkway is a mat that picks up pressure from footprints and gives us information about how the person is walking. All participants will be measured in the three different supports. Participants will also be asked to rate the difficulty of walking and any pain experienced whilst walking in the different supports. Patients will be issued with one of the supports at the end of the study and they will be able to decide which one. Participants who are agreeable will also have ankle strength measured after the walking assessments. There will be a single session of research measurements timed to coincide with normal clinic appointments.

What are the possible benefits and risks of participating?
The walking assessments are not expected to cause any additional long-term problems or discomfort compared with patients who are not involved in the research as all patients will starting to increase their walking at this stage of recovery. Some people can find the early stages of walking on the injured ankle to be uncomfortable and it may be tiring. The ankle can also become swollen when the cast is removed. These symptoms are all common and expected when

starting to walk on the ankle again for the first time out of the cast. We cannot promise the study will help the participant, but the information we get from this study will help improve the treatment of people with ankle fractures in the future.

Where is the study run from?
Oxford Trauma Unit (UK).

When is the study starting and how long is it expected to run for?
From April 2012 to March 2013.

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

Who is the main contact?
Dr David Keene

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3.0

Study information

Scientific Title

The effects of different types of ankle support introduced 6 weeks after surgical internal fixation for ankle fracture on gait and pain: a randomized, cross-over study

Acronym
SAFER

Study objectives
We aimed to determine the effects of ankle supports on gait characteristics and pain during the immediate period of unrestricted weight-bearing 6 weeks after ankle internal fixation surgery in adults. We also hypothesized that there would be reduced ankle muscle strength and range of joint motion as well as pain in the injured ankle compared to the uninjured ankle and that this would be associated with gait abnormalities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service South Central (12/SC/0146) and Oxford University Hospitals NHS Trust, 10/04/2012

Study design
Randomized three-treatment three-period cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Internal fixation surgery for an isolated ankle fracture

Interventions
All participants will be measured in the three different supports:
1. The standard intervention was Tubigrip® (Mölnycke Health Care, Sweden), which is an elasticated compressive tubular bandage
2. Ankle stirrup brace (protect.Ankle air foam, Medi, Germany)
3. Removable below-knee walker boot (Jura Walker Fixed, Promedics, UK)

Intervention Type
Device

Primary outcome measure
Two interrelated gait primary outcomes were:
1. Step length: the distance one part of the foot moves during a step in relation to the same part of the foot in the contralateral limb
2. Single support time: the duration of time in the gait cycle when a single lower limb is in contact with the ground and solely supporting body weight

Secondary outcome measures
1. Step width (cm)
2. Walking velocity (m/s)
Gait measurements were made using the GAITRite® electronic walkway (CIR Symptoms, Havertown, PA).
3. A visual analogue (VAS) was used to quantify pain and perceived difficulty immediately after each ankle support was tested (0-100; 'no pain' or 'no difficulty' and scored as 0 at one end and 'worst pain possible' or 'impossible', scored as 100)
4. Persisting and significant pain was considered an adverse event

Overall study start date
10/04/2012

Completion date
31/03/2013

Eligibility

Key inclusion criteria
Adults aged 18 years or over who had undergone internal fixation surgery for an isolated ankle fracture. On the day of study assessments, at the 6-week postoperative review, the orthopedic trauma surgeon seeing the participant approved removal of any ankle immobilizing device for at least short time periods and weight bearing as tolerated.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
18

Key exclusion criteria
1. Patients with a AO type C/supra-syndesmotic ankle fracture
2. Inability to walk outdoors unaided prior to fracture
3. Severe mental health disorder

4. Dementia
5. Neurological disorder
6. Any previous severe lower limb fracture
7. Open wounds below the knee of the injured limb
8. Acute or uncontrolled illness
9. Unable to safely walk 10 m without physical support from another person

Date of first enrolment
10/07/2012

Date of final enrolment
07/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Trauma Unit
John Radcliffe Hospital
Oxford University Hospitals NHS Trust
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Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (supported by Oxford Musculoskeletal Biomedical Research Unit)

Results and Publications

Publication and dissemination plan
The results will be presented at national and international medical meetings and in research journals. Participants wishing to be told about what we learn from the study will be contacted once the findings are made public.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No