ISRCTN13706230 https://doi.org/10.1186/ISRCTN13706230

A study of two different types of routinely used casts for people who have fractured their wrists

Submission date
22/12/2016

Recruitment status
No longer recruiting

Registration date
16/02/2017

Overall study status
Completed

Last Edited
27/04/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Wrist fractures are the most common fracture sustained by the adults. The majority of wrist fractures can be treated without surgery, usually by immobilising the wrist (holding it in place) with a cast. The most commonly used casts in the UK are products based on Plaster-of-Paris or fibre glass. Woodcast is an alternative product for use in casts. It is made from woodchips and aims to improve patient comfort whilst being more environmentally friendly that traditional materials used. The study will compare casting using the traditional fibre glass to those using Woodcast. In order to see if a large full-scale study looking at this is possible, a small study must first be done to see if it would be possible. The aim of this study is to look at how easy it is to recruit participants to a study comparing fibre glass and Woodcast casting in order to see if a full scale trial would be possible.

Who can participate?
Patients aged 16 years and over who have a broken wrist.

What does the study involve?
Initially, patients attend the accident and emergency department with their injury. If the patient has a broken wrist then a temporary plaster cast is applied and they are asked to attend an outpatient clinic appointment 24-72 hours later. At this appointment, patients who agree to take part have an x-ray taken of their wrist and answer some questions about how they were before the injury and their quality of life. Participants are then randomly allocated to one of two groups. Those in the first group have the standard (fibre glass) treatment and those in the second group have the Woodcast treatment. Two weeks later, participatns attend another clinic appointment where they have their cast changed (fibre glass) or remoulded (Woodcast) if required. They also complete questionnaires about their pain levels, comfort and satisfaction with their treatment. After five weeks, participants have their cast removed and undergo another X-ray to check the bones have repaired well. Finally, after three months, participants receive a questionnaire in the post to fill in and return. They are also asked about any complications they have encountered since leaving outpatients, such as if they have had to visit their GP or a physiotherapist.

What are the possible benefits and risks of participating?
There are no direct benefits to the participant for taking part in the trial however the information from this study may help to improve treatment for future patients with similar injuries. It will also provide valuable information on best use of resources within the NHS. The treatments that all participants will receive in this study are already available in the UK and so there are very few risks associated with the study, such as the risk of bones moving beneath the cast or from low dose of ionising radiation during x-rays.

Where is the study run from?
1. Oxford University Hospital (UK)
2. Walsgrave General Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2016 to June 2018

Who is funding the study?
Onbone Oy (UK)

Who is the main contact?
Mr Stephen Gwilym
steve.gwilym@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Stephen Gwilym

ORCID ID
http://orcid.org/0000-0002-1323-8646

Contact details
Oxford Trauma Unit
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU
+44 (0)7554 669554
steve.gwilym@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0

Study information

Scientific Title
Woodcast vs Standard casting material for the immobilisation of wrist fractures treated non-operatively – A randomised feasibility trial to see if patients agree to be randomised and accept the cast allocated

Acronym
WOODCAST

Study objectives
Research question:
It is feasible to recruit a fully randomised trial comparing Woodcast splints against conventional casting methods?

Hypotheses:
1. Woodcast splinting will not result in higher rates of fracture displacement compared against conventional casting methods within the feasibility study population (clinical efficacy)
2. There will be no difference in the patient reported experience of their period of immobilisation, between the two casting methods within the feasibility study population (patient satisfaction)
3. There will be no difference in the distribution of patient-reported functional outcome and quality of life measures between the two casting methods within the feasibility study population (patient outcome)
4. There will be no difference in the rate, or form of, complications experienced by the subjects exposed to the two casting methods within the feasibility study population (patient safety)

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands Leicester South REC, 27/03/2017, ref: 17/EM/0103

Study design
Multi-centre randomised parallel feasibility study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Fractured distal radius (broken wrist)

Interventions
Initially, patients attend the accident and emergency department with their injury. If the patient has fractured their distal radius (broken their wrist) they have a temporary plaster cast applied at the department and then need to attend an outpatient clinic 24-72 hours later. At this first outpatient review routine X-rays are taken and the participant is asked about their pre-injury status. They are then asked to fill out a Patient Rated Wrist Evaluation (PRWE) and an EQ-5D-5L questionnaire.

Participants are then randomised to one of two groups via the use of a centralised computer randomisation service RRAMP (https://rramp.octru.ox.ac.uk) provided by the Oxford Clinical Trials Research Unit (OCTRU). Randomisation will be stratified by age and whether or not the wrist was initially manipulated in the emergency department, using a variable block size to ensure the participants from each study site have an equal chance of receiving each intervention.

Group 1: Participants have the Standard (fibre glass) treatment applied as per local hospital procedures.

Group 2: Participants have the Woodcast treatment applied as per local hospital procedures.

At 2 weeks(+/-5 days) post randomisation participants attend the outpatients clinic again and if required, have their cast changed (fibre glass) or remoulded (Woodcast). Further questionnaires relating to the assessment of pain, comfort and satisfaction, and specifically the cast will be carried out.

At 5 weeks (+/-14 days) post randomisation the participant has their cast removed and another X-ray to check the bones have repaired well. They will also be asked the same questions as at their 2 week visit.

Finally, after 3 months (+/-3 weeks) post randomisation, the participants receive a PRWE and EQ-5D-5L questionnaire in the post to fill in and return. They are also asked about any complications they have encountered since leaving outpatients, such as if they have had to visit their GP or a physiotherapist.

Intervention Type
Procedure/Surgery

Primary outcome measure
Recruitment rate is determined from the number of eligible participants who consent to taking part in the study.

Secondary outcome measures
1. Wrist function is assessed using the Patient Rated Wrist Evaluation (PRWE) which is a validated questionnaire consisting of 15 items specifically related to the function of the wrist. It is measured at baseline and three months

2. Health related quality of life is assessed using the EQ-5D-5L which is a validated questionnaire relating to daily activities with a 5-level answer possibility, which will be converted into multi-attribute utility scores using an established algorithm at baseline and three months
3. Complication rate is assessed by patient review and the need for further follow up (physiotherapy etc) at three months
4. Radiographic evaluation: Standard posterior-anterior and lateral radiographs will be taken at baseline and at the routine follow-up appointment 5-weeks after the injury

Overall study start date
12/12/2016

Completion date
28/06/2018

Eligibility

Key inclusion criteria
1. Sustained a fracture of the distal radius, which is defined as a fracture within or equal to 3 cm of the radio-carpal joint
2. Over the age of 16
3. Able to give informed consent
4. The treating outpatient clinician believes that they would not benefit from surgery in the form of further manipulation of the fracture under anaesthetic or the insertion of metalwork
5. The patient is required to have a change of cast at the initial outpatient review

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Total final enrolment
120

Key exclusion criteria
1. The injury is more than one week old
2. The fracture extends more than 3 cm from radio carpal joint
3. The fracture is open
4. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as cognitive impairment
5. The patient sustained fractures to other areas of the body at the time they broke their wrist

Date of first enrolment
19/06/2017

Date of final enrolment
12/03/2018

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals,
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Royal Berkshire Hospital
Craven Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Nottingham University Hospitals
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
University of Oxford, Joint Research Office, Block 60
Churchill Hospital
Oxford
England
United Kingdom
OX3 7LE
+44 (0)1865 572245
ctrg@admin.ox.ac.uk

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Onbone Oy

Results and Publications

Publication and dissemination plan
A scientific report, suitable for publication in a peer-reviewed journal, will be prepared by the trial management team at the completion of the trial.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
Individual raw data will not be available but it will be analysed as a whole and results published.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2020	27/04/2021	Yes	No
HRA research summary			28/06/2023	No	No