ISRCTN11980540 https://doi.org/10.1186/ISRCTN11980540

Comparison of surgical procedures for patients with a fracture of the wrist

Submission date
02/08/2016

Recruitment status
No longer recruiting

Registration date
03/08/2016

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
All adult patients with a broken wrist (fracture of the distal radius) are given a temporary wrist support and referred to the local fracture service for treatment. Most broken wrists can be treated without the need for surgery. However, for the more serious wrist injuries, the treating surgeon may recommend an operation to restore the normal position of the wrist bones. This study is comparing two different ways of holding the broken bones in the best position while they heal. They are both used routinely throughout the NHS, but the most effective technique is unknown. The first technique involves the application of a plaster cast which is shaped (moulded) over the skin to hold the bone fragments in position. The second technique involves the surgical fixation of the bone fragments using metal wires (K-wires). The aim of this study is to find out whether surgical fixation of the broken bones of the wrist is more effective than plaster cast treatment.

Who can participate?
Patients aged 16 years and over who are having surgery to treat a broken wrist.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have a plaster cast shaped (moulded) over the skin to hold the bone fragments in position. The cast remains in place for around 4-6 weeks. Those in the second group undergo surgical fixation of the bone fragments using metal wires (K-wires). During this surgery smooth wires with a sharp point are passed across the fracture site through the skin to hold the bone fragments in position while they heal. A plaster cast is applied over the top of the wires to hold the wrist joint still, but the cast does not have to be moulded into position as the wires themselves hold the bone in place. The surgical and research team assess all patients, look at an x-ray and make a record of any early complications at 6 weeks, according to standard clinical procedure. Patients are also asked to report their own recovery using a questionnaire at 3 months, 6 months and 12 months after the treatment. The questionnaire also asks about the patient s wrist function, their general quality of life and any costs they have incurred related to their injury.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved for participants taking part in this study.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
July 2016 to August 2020

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Marta Campolier, drafft2@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Marta Campolier

Contact details
Nuffield Department Of Orthopaedics
Rheumatology and Muscoloskeletal Sciences
University of Oxford
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 227912
drafft2@ndorms.ox.ac.uk

Type(s)
Scientific

Contact name
Ms Bojana Selinsek

Contact details
Nuffield Department Of Orthopaedics
Rheumatology and Muscoloskeletal Sciences
University of Oxford
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 227912
drafft2@ndorms.ox.ac.uk

Additional identifiers

Study information

Scientific Title
Distal Radius Acute Fracture Fixation Trial 2

Acronym
DRAFFT2

Study objectives
Null hypothesis:
There is no difference in the Patient Rated Wrist Evaluation score (PRWE) one year post-injury between adult patients with a dorsally displaced fracture of the distal radius treated with plaster cast fixation versus K-wire fixation.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/152701

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford B Research Ethics Committee, 06/10/2016, ref: 16/SC/0462

Primary study design
Interventional

Study design
Multi-centre randomized parallel trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dorsally displaced fracture of the distal radius

Interventions
Participants are randomised to one of two groups, stratified by centre, intra-articular extension of the fracture and age of the patient (above or below 50 years).

K-wire Fixation group:
The wires are passed through the skin over the dorsal aspect of the distal radius and into the bone in order to hold the fracture in the correct (anatomical) position. The size and number of wires, the insertion technique and the configuration of wires will be left entirely to the discretion of the surgeon. A plaster cast will be applied at the end of the procedure to supplement the wire fixation as per standard surgical practice. This cast holds the wrist still and is left on until the wires are removed at the follow-up appointment.

Plaster Cast group:
This technique involves the application of a plaster cast which is shaped (moulded) over the skin to hold the bone fragments in position. The plaster cast will remain in situ for 4-6 weeks.

The study follow-up will range from events and at activities at the routine 6 week follow-up appointment. During this appointment radiographs and a short questionnaire on complications. This complications questionnaire will be completed by the Research Associate. The study follow-

up will also require patients to complete questionnaires for Patient Rated Wrist Evaluation, EuroQolEQ-5D, complications and resource use at 3, 6 and 12 months post-operatively.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Wrist function is measured using the Patient Rated Wrist Evaluation (PWRE) at baseline, 3, 6 and 12 months post-operatively.

Key secondary outcome(s)
1. Quality of life is measured using the EQ-5D at Baseline, 3, 6 and 12 months post-operatively.
2. Complications are measured using a questionnaire filled in by either a research associate at 6 weeks. In addition, complications will also be measured using a questionnaire completed by the patient at 3, 6 and 12 months post-operatively.
3.Radiographic evaluation will be used to assess the quality of reduction at baseline, 6 weeks and 12 months after the injury
4. Resource use will be monitored for the economic analysis. Unit cost data will be obtained from national databases such as the BNF and PSSRU Costs of Health and Social Care. Where these are not available the unit cost will be estimated in consultation with the UHCW finance department. The cost consequences following discharge, including NHS costs and patients' out-of-pocket expenses will be recorded via a short questionnaire which will be administered at 3, 6 and 12 months post surgery. Patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Sustained a dorsally displaced fracture of the distal radius, which is defined as a fracture within 3 cm of the radio-carpal joint.
2. Aged of 16 and able to give informed consent.
3. The treating Consultant Surgeon believes that they would benefit from manipulation of the fracture.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex

All

Total final enrolment
890

Key exclusion criteria
1. Injury is more than two weeks old
2. Fracture extends more than 3 cm from radio carpal joint
3. Fracture is open with a Gustillo grading greater than
4. Articular surface of the fracture (specifically the radio-carpal joint) cannot be reduced by indirect techniques. In a small number of fractures, the joint surface is so badly disrupted that the surgeon will have to open up the fracture in order to restore the anatomy.
5. Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as cognitive impairment

Date of first enrolment
31/10/2016

Date of final enrolment
05/04/2019

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/01/2022	27/10/2022	Yes	No
Results article		01/02/2022	27/10/2022	Yes	No
Protocol article	protocol	23/03/2019	09/04/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Radiographic analysis	13/02/2024	12/09/2024	Yes	No
Statistical Analysis Plan	Statistical and health economic analysis plan	11/06/2020	12/09/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes