ISRCTN31379280 https://doi.org/10.1186/ISRCTN31379280

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

Submission date	Recruitment status
23/03/2010	No longer recruiting
Registration date	**Overall study status**
29/03/2010	Completed
Last Edited	**Condition category**
21/04/2016	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fractures of the wrist are extremely common injuries. If the broken bones have stayed in their original place, then the fracture can usually be treated in a plaster cast or splint. However, some 'unstable' fractures (where the broken bones have been displaced) might need to be fixed back into place with an operation. The two most commonly used techniques in the UK are fixation with wires inserted through the skin (a simple and well-established method), and fixation with a plate which is applied to the surface of the bone with special screws (a very modern, potentially advantageous but expensive method). The aim of this study is to compare these two techniques.

Who can participate?
Patients aged over 18 with a wrist fracture

What does the study involve?
Participants are randomly allocated to be treated with either the wire fixation or the plate fixation technique. Before the operation and at three occasions after the operation (3 months, 6 months and 1 year), the patients' wrist function and quality of life are assessed. X-rays are taken at 6 weeks and 1 year to check if healing has occurred. A record is kept of any complications which occur after the operation. The patients are also asked to provide information about any out-of-pocket expenses they might have had in the period after the operation as a result of the injury (for instance whether they had to see a physiotherapist or had a cleaner for a while). The results of all these measurements are then used in two ways: to determine if there is a difference in effectiveness of the two fixation methods and what the most cost-effective method is, bearing in mind the quality of life of the patients.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
July 2010 to December 2013

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Study website
http://www.warwick.ac.uk/go/drafft

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/116/97

Study information

Scientific Title
A randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a displaced fracture of the distal radius

Acronym
DRAFFT

Study objectives

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 locking-plate fixation versus K-wire fixation.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0811697
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0012/52041/PRO-08-116-97.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry Research Ethics Committee, 24/02/2010, ref: 10/H1210/10

Study design
Multicentre randomised double-blind clinical 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

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

Interventions
K-wire Fixation:
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.

Volar locking plate:
The locking-plate is applied through an incision over the volar (palm) aspect of the wrist. Again, the details of the surgical approach, the type of plate, and the number and configuration of screws will be left to the discretion of the surgeon. The screws in the distal portion of the bone will be fixed-angle, i.e. screwed into the plate, but this is standard technique for the use of these plates. The type of proximal screw will be left to the discretion of the surgeon; these may be

locking or non-locking screws as the bone in this area provides a much better purchase for the screws. Some surgeons use a temporary plaster cast to hold the patients wrist still but the fixed-angle stability provided by the locking-plate is generally sufficient to allow early controlled range-of-movement exercises. The use or otherwise of a cast will again be left to the discretion of the surgeon as per usual practice.

The treatment takes approximately 1 hour. All patients will be followed-up for 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Primary outcome measure as of 24/01/2012:
Patient Rated Wrist Evaluation (PWRE). The PRWE score is a validated questionnaire which is self-reported (filled out by the patient). It consists of 15 items specifically related to the function of the wrist. This data will be collected at baseline, 3, 6 and 12 months post-operatively. The PRWE is the most sensitive outcome measure for patients sustaining this specific injury. Analysis will be performed on the complete data set as well as on the subgroup of patients over the age of 50 years.

Previous primary outcome measure:
Patient Rated Wrist Evaluation (PWRE). The PRWE score is a validated questionnaire which is self-reported (filled out by the patient). It consists of 15 items specifically related to the function of the wrist. This data will be collected at baseline, 3, 6 and 12 months post-operatively. The PRWE is the most sensitive outcome measure for patients sustaining this specific injury.

Secondary outcome measures
1. Disabilities of Arm, Shoulder and Hand score (DASH) - the DASH Outcome Measure is a 30-item, self-report questionnaire designed to provide a more general measure of physical function and symptoms in people with musculoskeletal disorders of the upper limb
2. EQ-5D - a validated, generalised, quality of life questionnaire consisting of 5 domains related to daily activities with a 3-level answer possibility. The combination of answers leads to the QoL score.
3. Complications - all complications will be recorded
4. Radiographic evaluation - standard posterior-anterior and lateral radiographs will be taken at baseline, 6 weeks and 12 months after the injury. These radiographs are those routinely used for the investigation of patients with a suspected fracture of the distal radius and for the follow-up of such patients following any intervention, so there will be no need to request any additional or special investigations. Although the technique for taking these radiographs is well-established, each centre will be provided with a written protocol to ensure that exactly the same views are obtained at each hospital. An assessment of the quality of the reduction, and the risk of subsequent loss of reduction, will be made using the criteria recommended by Mackenney et al.
5. 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.

Overall study start date

01/07/2010

Completion date
31/12/2013

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. The treating Consultant Surgeon believes that they would benefit from operative fixation of the fracture
3. Aged over 18 years (either sex) and able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Minimum of 390

Key exclusion criteria
1. The fracture extends more than 3 cm from radio-carpal joint
2. The fracture is open with a Gustillo grading greater than 1
3. The articular surface of the fracture 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 under direct vision)
4. There are contra-indications to surgery, defined as:
4.1. Severe cardiac impairment, e.g. heart or valve replacement, arrhythmia, previous myocardial infarction
4.2. Severe respiratory impairment, e.g. chronic obstructive pulmonary disease, asthma that has required hospital admission
4.3. Any other systemic medical condition that would produce a specific contraindication to a general anaesthetic
5. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as cognitive impairment or intravenous drug abuse

Date of first enrolment
01/07/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
Not defined

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http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/09/2011		Yes	No
Results article	results	05/08/2014		Yes	No
Results article	results	01/02/2015		Yes	No