

Distal Radius Internal Fixation Trial

Submission date 14/05/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/02/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9191

Study information

Scientific Title

Surgical interventions for treating intra and extra-articular distal radius fractures: a randomised controlled trial of internal fixation with plate & screws versus percutaneous K-wiring

Acronym

Distal Radius Internal Fixation Trial

Study objectives

The aim of this study is to assess the functional benefit/value for money of fixation of low-impact wrist fractures using a volar plate compared to K wiring.

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H1203/19

Study design

Randomised; Interventional and Observational; Design type: Not specified, Treatment, Qualitative

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

Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

K-wires, The number of K-wires used and whether they are buried or not depends on the surgeon's preference.; Volar plate, The volar approach and a fixed angled locking plate should be used for patients in the plate treatment group.; Follow Up Length: 12 month(s)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Disability of Arm Shoulder and Hand Questionnaire functional score at baseline, 3, 6 and 12 months

Secondary outcome measures

1. EQ5D Questionnaire at baseline, 3, 6 and 12 months
2. Patient Diary kept for three most post-surgery
3. Patient Related Wrist Evaluation Questionnaire functional score at baseline 3, 6 and 12 months
4. Resource Usage Questionnaire at baseline, 3, 6 and 12 months
5. X-ray review at 3 and 12 months

Overall study start date

01/10/2010

Completion date

16/12/2013

Eligibility**Key inclusion criteria**

1. The patient is skeletally mature (at least 16 years old).
2. The patient has had a low-impact trauma resulting in an isolated distal radius fracture as confirmed by Xray. Low impact fractures are those sustained in a fall from no higher than a standing position and at a velocity not above that of running.
3. The fracture is no more than 2 weeks old at the time of surgery.
4. There is no definite contraindication to, or definite indication for, one particular intervention and thus the surgeon is uncertain as to whether to treat the fracture with a plate or with wiring.
5. NonEnglish speaking patients may be entered if there is a translator present at the time of consent and they have someone to help them fill in the questionnaires

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 169; UK Sample Size: 169

Total final enrolment

170

Key exclusion criteria

1. The patient has not given informed consent.
2. The patient is a child under 16 years of age.
3. The patient is not medically fit for surgery.

4. The fracture has previously been treated.
5. There is major displacement of articular fragments or obvious ligament injury.
6. The fracture is not displaced or is minimally displaced so that conservative treatment rather than surgery is considered appropriate.
7. If the fracture is accompanied by a compound injury with a Gustillo grading of 2 or higher.
8. The patient is unlikely to or unable, due to a cognitive impairment (as defined by the medical team responsible, this includes drug/alcohol abuse), to provide consent and complete questionnaires.
9. If the patient is not able to complete a year of followup

Patients not eligible for the study will receive clinical care and treatment as they would per normal clinical practice.

Date of first enrolment

01/10/2010

Date of final enrolment

16/12/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Twmpath Lane

Oswestry

United Kingdom

SY10 7AG

Sponsor information

Organisation

The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust(UK)

Sponsor details

Twmpath Lane

Oswestry

England

United Kingdom

SY10 7AG

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/030mbcp39>

Funder(s)

Funder type

Government

Funder Name

NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0408-16214

Results and Publications

Publication and dissemination plan

Not provided at time of registration

2017 results presented at the British Orthopaedic Association conference in <https://www.boa.ac.uk/uploads/assets/uploaded/d9355f25-8365-444d-b6648de243234932.pdf>, see abstract 735

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration