ISRCTN07813725 https://doi.org/10.1186/ISRCTN07813725

Distal Radius Internal Fixation Trial

Submission date
14/05/2014

Recruitment status
No longer recruiting

Registration date
14/05/2014

Overall study status
Completed

Last Edited
19/02/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Simon John Pickard

Contact details
Twmpath Lane
Oswestry
United Kingdom
SY10 7AG
+44 1691 404226
simon.pickard@rjah.nhs.uk

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. Lowimpact 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 kwiring.
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