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Clinical study of the volar locking plate for distal radial fractures

Submission date	Recruitment status	[ ] Prospectively registered
17/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/10/2013	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07OR003

Study information

Scientific Title
Unstable fractures of the distal radius: a randomised prospective clinical study comparing their treatment with volar locking plate and conventional method

Study objectives
This study will compare the outcome of displaced distal radial fractures when treated with a volar locking plate (the Distal Volar Radius [DVR®]) or the conventional method which involves percutaneous wires +/- an external fixator.

Our primary research objective is to determine whether the use of volar locking plates improves functional outcome and allows for an earlier return to normal activities and work.

As a secondary objective, we aim to determine through economic evaluation, whether the use of volar locking plates for distal radial fractures is of financial benefit to the health service and society in general.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Nottinghamshire Research Ethics Committee approved on the 6th September 2007 (ref: 07/H0407/39)

Study design
Pragmatic randomised single centre controlled parallel group surgical 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
Distal radius fracture

Interventions

The intervention consists of surgical fixation of the distal radius fracture in a patient who fulfils the trial inclusion and exclusion criteria with a radial volar locking plate or the established conventional method involving percutaneous wires +/- an external fixator.

The health technology under assessment is the radial volar locking plate, a type of orthopaedic implant with locking screws which aid the reduction and stabilisation of distal radius fractures. We compare this to the established conventional methods (percutaneous wires and/or an external fixator device).

The plate chosen for this trial is the Distal Volar Radius or DVR® plate, which is in common use across the United Kingdom. Instrumentation also includes smooth 1.6 mm Kirschner wires and the standard AO external fixator, as appropriate. All are currently in use within the NHS, CME licensed and will not require MHRA authorisation.

The total duration of follow-up for each participant is one year post-surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Function of the limb following a surgically treated distal radius fracture. As a measure of function we selected the Hand Health Profile forming part of the Patient Evaluation Measure (PEM). Expected duration of patient participation will be one year. Follow up and data collection will be performed at 6 weeks, 12 weeks and 1 year.

Secondary outcome measures
1. Clinical measurements: grip strength and range of motion
2. Radiographic parameters: radial length, palmar tilt, radial inclination and articular gaps/steps less or equal to 2 mm
3. Quality of life: as assessed via the EUROQUOL EQ-5D and 12-item short form health survey (SF-12) scores

Expected duration of patient participation will be one year. Follow up and data collection will be performed at 6 weeks, 12 weeks and 1 year.

Overall study start date
11/02/2008

Completion date
30/08/2010

Eligibility

Key inclusion criteria
1. Fractures which the referring physician considers require operative intervention
2. Configuration is such that the fracture would be amenable to stabilisation via volar locking plate (not massively comminuted)
3. Adults (skeletally mature) with high demand requirements of their wrist in whom the

radiological appearance of the bone suggests that it is robust enough to tolerate internal fixation; and in whom the fracture pattern at presentation fulfils the criteria as described below
4. Fractures of the distal radius which are:
4.1. Dorsally displaced extra-articular fractures (with or without an undisplaced intra-articular component) with dorsal cortical comminution as seen on the lateral radiograph
4.2. Displaced intra-articular fractures with an articular step or gap in the radio-carpal joint surface
5. Skeletally mature adults, minimum age 16 years and above, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
122

Key exclusion criteria
1. Patients with concomitant systemic diseases (diabetes with vascular or neurological complications, advanced cardiac, pulmonary or neurological disease)
2. Proximal metaphyseal fractures (more than one inch or 2.5 centimetres from the articular surface)
3. Open fractures
4. Smith's and volar Barton's configuration
5. Previous fractures of the distal radius of the same or contra-lateral limb less than six months old
6. Significant pre-existing radiological abnormality
7. Multiply injured
8. Bilateral injuries
9. Patients who are unable to consent for themselves to treatment
10. Patients who may have difficulties in adequate understanding of English

Date of first enrolment
11/02/2008

Date of final enrolment
30/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Department of Orthopaedic & Accident Surgery
Nottingham
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Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
E11 Curie Court
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Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.uk/nch/randd/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Nottingham University Hospitals NHS Trust (UK)

Funder Name
Nottingham University Hospitals Charity via the Hand Research Fund (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?
Results article	results	02/10/2013		Yes	No