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Open reduction and internal fixation versus closed reduction and casting for highly comminuted, intraarticular fractures of the distal radius

Submission date
18/07/2008

Recruitment status
No longer recruiting

Registration date
31/07/2008

Overall study status
Completed

Last Edited
30/12/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

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
DRKS00000041

Study information

Scientific Title
Open reduction and internal fixation versus closed reduction and casting for highly comminuted, intraarticular fractures of the distal radius

Acronym
ORCHID

Study objectives
Open reduction and volar plate fixation of AO C-type fractures of the distal radius in patients >65 years will lead to a difference in Short-Form 36 (SF-36) Physical Component Scores (PCS) of 2.5 ± standard deviation 10 points after one year of follow-up, compared to closed reduction and cast stabilisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board (IRB) of the University of Ulm. Approved. (ref: 63/08)
2. Local IRBs of the participating institutions are currently reviewing the protocol. It is anticipated that all approvals will be provided by mid August 2008 (as of 18/07/2008).

Study design
Pragmatic, randomised, controlled, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Comminuted, intraarticular distal radial fractures in the elderly

Interventions

Target number of participants at completion of the trial is 2 x 252 (n = 504). Assuming a 10% drop-out rate, 560 patients will be recruited in total.

Intervention A: Open reduction and internal fixation with volar locking plates
Intervention B: Closed reduction and cast stabilisation

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
SF-36 PCS (V5, V6)

Timepoints:
V1 = Baseline
V2 = Intervention
V3 = Day 1 (+ 1 day)
V4 = 2 weeks (+/- 3 days)
V5 = 3 months (+/- 1 week)
V6 = 1 year (+/- 2 months)

Secondary outcome measures
1. All other SF-36 domains and SF-36 Mental Component Score (MCS) (V5, V6)
2. Disability of the Arm, Shoulder and Hand (DASH) questionnaire (V5, V6)
3. EuroQol 5D (EQ-5D) health outcome tool (V3, V5, V6)
4. Complications and serious adverse events (SAE), specifically treatment failures and/or surgical revisions, onset of complex regional pain syndrome (CRPS) type I (Duration of follow-up: 1 year [V6])
5. Wrist range of motion (V5, V6)
6. Need for pain medication (Total duration of follow-up: 1 year [V6])
7. Independent living (V3, V6)

Timepoints:
V1 = Baseline
V2 = Intervention
V3 = Day 1 (+ 1 day)
V4 = 2 weeks (+/- 3 days)
V5 = 3 months (+/- 1 week)
V6 = 1 year (+/- 2 months)

Overall study start date
01/09/2008

Completion date
01/02/2012

Eligibility

Key inclusion criteria

1. Both males and females, age >65 years
2. Patients with isolated, closed, unilateral, radiologically confirmed distal radial fractures (AO 23 C1 - C3, as classified by the surgeon in charge)
3. Patients must have sustained their fracture <1 week before presentation to the centre
4. Patients who have not received specific treatment (e.g. prior attempt of closed reduction and casting)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
560

Total final enrolment
149

Key exclusion criteria
1. Clear indication for surgery (e.g. open fracture or severe soft tissue damage)
2. Clear contraindication for surgery (e.g. unacceptable anesthesiological risk)
3. Presence of factors associated with an unfavourable risk-benefit-ratio for surgery (e.g. poor skin and soft tissue conditions)
4. Mental disorders
5. Previous participation in the trial, or enrolment in another interventional study on distal radial fractures

Date of first enrolment
01/09/2008

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Germany

Study participating centre
Department of Trauma, Hand, and Reconstructive Surgery
Ulm
Germany
89075

Sponsor information

Organisation
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

Sponsor details
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Sponsor type
Government

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https://ror.org/018mejw64

Funder(s)

Funder type
Government

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: DFG GE1105/6-1)

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	22/03/2011		Yes	No
Results article	results in German	14/11/2014	30/12/2020	Yes	No