

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 31/07/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 30/12/2020	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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 $2.5 \pm$ 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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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 anaesthesiological 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)

ROR

<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

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 in German	14/11/2014	30/12/2020	Yes	No
Protocol article	protocol	22/03/2011		Yes	No