A randomized trial comparing plaster cast immobilization versus operation in elderly patients with distal radius fractures

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The aim of the proposed study is to improve functional outcome using locking angle-stable screw-plate osteosynthesis compared to plaster cast immobilization.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON35514

Source
ToetsingOnline

Brief title
RADIUS

Condition

- Fractures

Synonym
wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: distal radius, fracture, plaster cast immobilization, plate fixation

Outcome measures

Primary outcome

Primary outcome parameters: Disability of Arm, Shoulder and Hand (DASH) score,

Musculoskeletal Function Assessment (MFA)

Secondary outcome

General and functional outcome parameters: Short Form 12 (SF-12) health survey

questionnaire, and Patient Related Wrist Evaluation (PRWE),

Range of motion,

Pain level (VAS),

Cost-effectiveness analysis,

Radiographic analysis using Lidstrom score

Complication rate.

Study description

Background summary

Complication rate for treatment of displaced intra-articular distal radius fractures is low, although functional disability remains a significant problem with up to 30% of patients suffering long-term functional restrictions after conservative treatment. Whether operative correction improves this functional outcome compared to conservative treatment remains unclear.

Study objective

The aim of the proposed study is to improve functional outcome using locking angle-stable screw-plate osteosynthesis compared to plaster cast immobilization.

Study design

Prospective randomized controlled clinical trial

Intervention

Plaster cast immobilization is compared to open reduction and internal fixation.

Study burden and risks

The expectations of this study is that operative treatment is beneficial for the patient with a distal radius fracture. This risk of specific complications is low and generally similar in both treatment options. Functional results due to improved congruency of the radius joint is hypothesized to be higher in the operative group. Moreover, the burden of the study is not much higher compared to standard treatment. Follow-up is standardized according to current trauma guidelines. Literature indicates that both treatment options from the study are accepted for displaced distal radius fractures. No clear advantage for one treatment options is found at present in the literature, although there is no level I evidence present. Both treatment options have their known complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age > 55 years
2. Primary displaced unilateral fracture of distal radius (open fractures are included)
a. AO (Arbeitsgemeinschaft fur Osteosynthesefragen) type A2
b. AO type A3
c. AO type B1
d. AO type C1
e. AO type C2
3. Independent for activities of daily living (yes/no question)
4. Inadequate reduction of distal radius fracture at emergency department (For specific criteria see below)
and/or
5. Inadequate reduction of distal radius at 1 week follow-up at the outpatient department: Therapeutic failure is defined as fracture displacement when the dorsal or volar angulations are more than 10º, intra-articular step-off > 2mm, or the ulnar variance is more than 5mm. This failure accounts for both redisplacement after initial adequate alignment during conservative treatment (including manipulative reduction) on the emergency department) and for secondary failure after surgical reduction.

Exclusion criteria

1. Fracture of contralateral arm
2. Other fractures at the ipsilateral arm (excluded carpal fractures)
3. Pre-existent abnormalities fractured distal radius
4. Primary unilateral fracture distal radius AO type A1, B2, B3 and C3
5. Pathological fractures (due to metastasis, secondary osteoporosis)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-10-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20952.068.07