A prospective, randomised multicenter controlled trial on the treatment of intra-articular distal radius fractures; open reduction and internal fixation with volair angle stable plating versus percutaneous reduction and fixation in combination with an external fixator

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31202

Source
ToetsingOnline

Brief title
MiniMax Study

Condition

- Bone and joint therapeutic procedures

Synonym
wrist fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: geen

Intervention

Keyword: Distal radius fractures, External fixation, Volair plate fixation, Wrist fractures

Outcome measures

Primary outcome

Functional outcome scores (DASH, MAYO wrist score) and patient satisfaction

score (SF 36), pain score (VAS)

Secondary outcome

Radiological findings, complications

Study description

Background summary

Fractures of the distal radius are a frequently seen common clinical problem al over the world. Almast 4000 distal radius fractures were diagnosed in The Netherlands in 2005. Because of an expected increase in eldery and the incidence of osteoporosis, the number of fractures will increase. Almost 60 % of the distal radius fractures are intra-articular fractures. Many different treatment options are used.
To avoid late complications like posttraumatic arthritis it is important to restore the intra-articular surface to its anatomic position, because deformity leads to a decrease in functionality of the wrist. For the first period after treatment it is important to choose a treatment option that will give the patient quick recovery of wrist function. For the instable fracture types a conservative treatment is not an option and those fractures should become operative treatment.
At this moment, there is no consensus about the different options of treatment.

Closed reduction and fixation with external fixation shows some good results.

The development of the volar angle stable locking plates a new treatment option can be used with less postoperative complications. Recovery of the intra articular deformity will give the fracture elements more stability after reposition.
These two treatment options have never been compared within a prospective, randomised controlled trial.

Study objective

The goal of this study will be to determine a functional benefit and an increase in patient satisfaction after a period of one year of open reduction and internal fixation (ORIF) by volar approach versus percutaneous reposition and fixation with external fixation as a treatment of dislocated intra-articular distal radius fractures

Study design

A multicenter prospective randomised controled trial. Intention to treat.

Intervention

Group A will get a treatment with ORIF (open reposition and internal fixation) and group B will get an external fixation

Study burden and risks

Both treatment options are already commonly used. Therefore the risks for the patients will be minimal. After a regular follow-up of 6 months patients come back for a final visit after one year. physical examination, two x-rays and scoringsformulars will be filled in.

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

age > 50
informed consent
dutch language
intra-articular fractures type AO B/C and Frykmann III, IV, VII and VIII
closed fractures and open fractures Gustillo gr 1/2

Exclusion criteria

Fractures > 14 days old
Gr 3 Gustillo classification
Pre-existent arthritis of the wrist
ASA IV-V
No informed consent

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:	Recruitment stopped
Start date (anticipated):	01-02-2008
Enrollment:	148
Type:	Actual

Ethics review

Approved WMO

Date:	06-09-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL18357.098.07