Minimax study; open reduction and internal fixation with volar fixed-angle plating vs percutaneous reduction and external fixation for displaced intra-articular fractures of the distal radius in the eldery

Published: 18-06-2008
Last updated: 13-12-2022

ORIF with volar fixed-angle plates and external fixation have a similar outcome as measured with the DASH score (and the Mayor Wrist Score).

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22659

Source
Nationaal Trial Register

Brief title
MiniMax-study

Health condition

Displaced intra-articular distal radius fractures in the eldery (gedisloceerde intra-articulare distale radius fracturen bij de oudere patienten)

Sponsors and support

Primary sponsor: Medical Center Haaglanden, Department of Surgery, Medical Center Haaglanden, Medical Ethical Committee Zuid-West Holland (METC)
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primairy outcome measures are:

- wrist function (DASH, Mayo Wrist Score)

- patient satisfaction (SF-36)

- pain sensation (VAS).

Secondary outcome

Secondary outcomes are:

- radiographic parameters

- the number of complications

Study description

Background summary

Fractures of the distal radius are a common clinical problem, frequently seen on the emergency department. Almost 60 % of all distal radius fractures represents intra-articular fractures. Because displaced intra-articular fractures of the distal radius are considered to be unstable, operative treatment is necessary for acceptable functional outcome after union. There is no consensus of best operative treatment of these fracture types. The traditional approach to treating intra-articular distal radius fractures has been external fixation.

In recent years, the use of volar, locked plates has gained popularity as a treatment option in the management of these fractures. This study aims to demonstrate a clinically significant difference using the Disability of Arm, Shoulder and Hand (DASH) score after one year. Open reduction and internal fixation using volar fixed-angle locking plates and percutaneous reduction and fixation with external fixation will be compared in an adequately powered, multicenter randomized controlled trial with 2 treatment arms. Clinical outcome will be measured using the DASH-score, the Mayo Wrist score, standard physical exam and radiographic criteria after 6 weeks, 3 months, six months and one year.

Study objective

ORIF with volar fixed-angle plates and external fixation have a similar outcome as measured with the DASH score (and the Mayor Wrist Score).

Study design

Post-operative controll-moments:

after 1 week, 6 weeks, 3 months, 6 months and one year

Intervention

This study will randomise between:

1. Open reduction and internal fixation via a volar approach using volar fixed-angle locking plates and

2. Closed reduction, percutaneous pinnen and fixation, and external fixation with additional adjuncts.

Contacts

Public
Medical Center Haaglanden
Lijnbaan 32

J. Keizer
Den Haag 2512 VA
The Netherlands
+31 (0)70 3302000
Scientific
Medical Center Haaglanden
Lijnbaan 32

J. Keizer
Den Haag 2512 VA
The Netherlands
+31 (0)70 3302000

Eligibility criteria

Inclusion criteria

1. All patients with a displaced intra-articular fracture of the distal radius.

2. More than 50 years old.

3. Compos Mentis.

4. Living in the Netherlands.

5. Informed Consent.

6. Closed fractures or open fractures Gustillo 1-2.

Exclusion criteria

1. a fracture older than 14 days.

2. Grade III open fractures.

3. ASA IV-V.

4. Participation in other studys.

5. Severe Wrist artrose or limited wrist motion before fracture.

6. Fractures on both sides (left and right).

7. Chronic substance abusus.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	148
Type:	Actual

Ethics review

Positive opinion

Date:	18-06-2008
Application type:	First submission

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
NTR-new	NL1302
NTR-old	NTR1350
Other	Medisch Ethische Toetsingscommissie Zuidwest Holland : 07-096
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Handoll HHG, Madhok R. Surgical interventions for treating distal radial fractures in adults (Review), The Cochrane Library 2005, Issue 2

Jupiter JB, L. H. (1993). The operative treatment of intraarticular fractures of the distal radius. Clin Orthop , 292: 48-61.

Nana AD, Joshi A, Lichtman DM. Plating of the distal radius.
J Am Acad Orthop Surg. 2005; 13; 159-171
Orbay JL, Fernandez DL. Volar fixed-angle plate fixation for unstable distal radius fractures in the elderly patiënt. J Hand Surg [Am]. 2004; 29; 96-102