

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 elderly

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22659

Bron

NTR

Verkorte titel

MiniMax-study

Aandoening

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

Ondersteuning

Primaire sponsor: Medical Center Haaglanden, Department of Surgery, Medical Center Haaglanden, Medical Ethical Committee Zuid-West Holland (METC)

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measures are:

- wrist function (DASH, Mayo Wrist Score)

- patient satisfaction (SF-36)

- pain sensation (VAS).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Post-operative control-moments:

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 abus.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2008
Aantal proefpersonen:	148
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	18-06-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1302
NTR-old	NTR1350
Ander register	Medisch Ethische Toetsingscommissie Zuidwest Holland : 07-096
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

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