

Wrist fractures treated with plaster cast or operation: what leads to the best outcome in patients older than 50 years?

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Open reduction and internal fixation (ORIF) using locking-plate distal radius osteosynthesis leads to an improved functional outcome (DASH score) in elderly (>50 years) (independent in activities of daily living) patients with a displaced distal...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29311

Bron

Nationaal Trial Register

Verkorte titel

RADIUS STUDY: Randomized Assessment of Distal radius fracture Interventions in Unstable Subtypes

Aandoening

distal radius
fracture
plate fixation
plaster cast immobilization

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameter/endpoint

Functional outcome parameters:

Disability of Arm, Shoulder and Hand (DASH) score, Musculoskeletal Function Assessment (MFA)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Open reduction and internal fixation (ORIF) using locking-plate distal radius osteosynthesis leads to an improved functional outcome (DASH score) in elderly (>50 years) (independent in activities of daily living) patients with a displaced distal radius fracture (AO type A2, A3, B1, C1, and C2).

Onderzoeksopzet

Follow-up 1 month, and 3, 6, 12 and 24 months

Onderzoeksproduct en/of interventie

Open reduction and internal fixation using locking-plate and angular stable screw fixation versus plaster cast immobilization

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 50 years
2. Primary displaced unilateral fracture of distal radius (open fractures are included)
 - a. AO (Arbeitsgemeinschaft für 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 10°, intra-articular step-off > 1mm, or the ulnar variance is more than 3mm.

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

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	NL1235
NTR-old	NTR1280
Ander register	MEC azM : 08-2-009
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A