

Functionele resultaten en complicaties bij patiënten die zijn behandeld voor polsbreuken met plaatfixatie.

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The newer dorsal locking plates will lead to comparable or improved outcomes in comparing with the volar locking plates in adult patients with unstable distal radius fracture or malunion.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23579

Bron

Nationaal Trial Register

Aandoening

Distal radius fractures are one of the most common fractures, representing 16% of all fractures treated by orthopaedic trauma surgeons. Most distal radius fractures can be treated with closed reduction (when it is displaced) and immobilization in a plaster cast. Indication for operative treatment is instability of the distal radius fracture leading to malunion with poor outcome. Various surgical interventions are available, in which open reduction and internal fixation by plates has gained widespread popularity. It is unknown which surgical treatment is considered as the most appropriate treatment for distal radius fractures.

Ondersteuning

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Overige ondersteuning: government funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The first objective of this retrospective study is to compare dorsal and volar plate fixation for the treatment of distal radius fractures in a large patient group.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Distal radius fractures are one of the most common fractures, representing 16% of all fractures treated by orthopaedic trauma surgeons. Most distal radius fractures can be treated with closed reduction (when it is displaced) and immobilization in a plaster cast. Indication for operative treatment is instability of the distal radius fracture leading to malunion with poor outcome. Various surgical interventions are available, in which open reduction and internal fixation by plates has gained widespread popularity. It is unknown which surgical treatment is considered as the most appropriate treatment for distal radius fractures.

Objectives:

The aim of this study is to compare dorsal plate fixation with volar plate fixation for the treatment of unstable distal radius fracture or malunion in a large patient group and determine which one is the most appropriate treatment, meaning fewer complications and better functional outcome.

Study design:

A retrospective comparison study.

Study population:

Patients of either sex from the age of 18 years or above who are been treated for their unstable distal radius fracture or malunion with open reduction and internal fixation, using dorsal or volar plate.

Main study outcomes:

Primary study outcomes: Disability of Arm, Shoulder and Hand (DASH) score, Patient Related Wrist Evaluation (PRWE) and complication rate.

Secondary study outcomes: range of motion, grip and pinch strength and radiographic analysis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All included patients have to undergo several examinations: filling out questionnaires, undergoing physical examination of both wrists and making radiographs of both wrists. The radiation exposure is almost negligible (< 1 mSv). The visit at MUMC will take in total 60 minutes. The patients will receive a bonus, if they complete all examinations.

Doel van het onderzoek

The newer dorsal locking plates will lead to comparable or improved outcomes in comparing with the volar locking plates in adult patients with unstable distal radius fracture or malunion.

Onderzoeksopzet

All study outcomes will be measured at one time point.

Primary study outcome:

The functional outcome will be measured with the use of the DASH score and PRWE. The DASH score is a self-reporting questionnaire which is the best scoring system to evaluate patients with disorders involving multiple joints of the upper limb. The DASH score ranges from 0 to 100, with lower numbers indicating a lower level of disability. PRWE score is also a self-reporting questionnaire and is the most responsive instrument for evaluating the outcome in patients with distal radius fractures. The total function on the PRWE scale ranges from 0 (normal wrist) to 150 (worst possible score).

Complications are categorized as major or minor. Minor complications include tendon irritation, superficial infections, and finger stiffness which were treated nonoperatively on an outpatient basis. Major complications include loss of reduction, malunion, nonunion, deep infection, neuropathy and tendon rupture which required hospitalization or reoperation.

Secondary study outcome:

Functional outcome:

1. Range of motion of the wrist will be evaluated by recording flexion-extension, pronation-supination, and radioulnar deviation with a standard goniometer;
2. Grip and pinch strength are going to be measured with a dynamometer and the values will be compared with those for the contralateral extremity.

Radiographic analysis:

Anteroposterior and lateral radiographs of the fractured and uninjured distal radius are going to be made for measurement of volar tilt, radial inclination, radial length, ulnar variance, and steps and gaps for intra-articular fractures. These radiographs of both wrists will be compared to each other, but also the first radiographs after the reduction will be compared.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients of either sex from the age of 18 years or above;
2. Operative treatment for unstable distal radius fracture or malunion by open reduction and internal fixation with dorsal or volar plate fixation;
3. At least 24 months of postoperative follow-up.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Open or bilateral fractures, previous fractures of the wrist at the ipsilateral or contralateral arm, wrist fractures in polytraumatized patients, other fractures at the ipsilateral arm, fractures associated with neurovascular injury;
2. Local disorders (e.g., tumors, Paget's disease);
3. Motor function disorders (e.g., central motor disorder, myasthenia gravis).

Onderzoekopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Parallel
Toewijzing: Niet-gerandomiseerd
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 28-11-2011
Aantal proefpersonen: 120
Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35181
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2967
NTR-old	NTR3114
CCMO	NL37589.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35181

Resultaten

Samenvatting resultaten

N/A