VIPER, operatie versus gips bij polsfracturen.

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Anatomic reduction and stable fixation of distal radius fractures by volar plating allows for early mobilization and therefore leads to a better function.

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

Samenvatting

ID

NL-OMON26639

Bron
Nationaal Trial Register

Verkorte titel
VIPER

Aandoening

Distal radius fractures

Ondersteuning

Primaire sponsor: Academic Medical Centre Amsterdam
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Disability of the Arm, Shoulder and Hand (DASH) questionnaire

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The ideal treatment for extra-articular distal radius fractures remains a controversial issue. Excellent results have been described both in patients treated with a plaster and in patients treated with open reposition and internal fixation (ORIF) with a volar locking plate. Recently, the use of Volar Locking Plates has become more popular, due to its better performance in osteoporotic bone. Moreover, anatomic reduction and stable fixation of these fractures allows for early mobilization and may theoretically lead to a better function.

Objective:

To compare the functional outcome of ORIF with a volar locking plate to closed reduction and plaster immobilisation in patients with extra-articular distal radius fractures.

Study design:

Multi Center Randomized Controlled Trial.

Study population:

All consecutive adult patients with an AO type A distal radius fracture which was successfully reduced within 12 hrs of presentation at Emergency department of the participating hospitals.

Intervention:

This study will randomise between open reduction and internal fixation with a volar locking plate and plaster immobilisation.

Main study parameters/endpoints:

Primary outcome: Disability of the Arm, Shoulder and Hand (DASH) score. Seconday outcome: Patient-Rated Wrist Evaluation score (PRWE). Quality of life (QoL SF-36), pain as indicated on a Visual Analogue Scale (VAS), Range of Motion (ROM), radiological outcome and complications.

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

Patients will be asked to return to the hospital for follow up at; one, three and six weeks and three, six and twelve months. During these visits patients will be asked about any complaints and/or complications and physical examination will be performed. The risks associated with the treatment under study comprise standard risk for undergoing a surgical procedure related to anaesthesia, post-operative pain and wound infection.

Doel van het onderzoek

Anatomic reduction and stable fixation of distal radius fractures by volar plating allows for early mobilization and therefore leads to a better function.

Onderzoeksopzet

1 week, 2 weeks, 6 weeks, 3 months, 6 months, 1 year.

Onderzoeksproduct en/of interventie

This study will randomise between open reduction and internal fixation with a volar locking plate and plaster immobilisation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients >18 years <75;

2. AO type A displaced distal radius fracture;

3. Fracture displacement is defined by the AO foundation as fragments not perfectly anatomically aligned;

4. Acceptable closed reduction obtained immediately after presentation at the Emergency Department (<12hrs).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with impaired wrist function prior to injury due to arthrosis/neurological disorders of the upper limb;

2. Open distal radius fractures;

3. Multiple trauma patients;

4. Other fractures in the affected extremity;

5. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician;

6. Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget’s disease, renal osteodystrophy, osteomalacia);

7. Patients suffering from connective tissue disease or (joint) hyperflexibility disorders such as Marfan’s, Ehler Danlos or other related disorders.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-10-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41583
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2966
NTR-old	NTR3113
CCMO	NL37754.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41583

Resultaten

Samenvatting resultaten
N/A