

# Operation or Plaster in Wrist Fractures

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Open reduction and internal plate fixation has a better functional outcome compared to closed reduction and plaster immobilisation.

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29516

### Bron

Nationaal Trial Register

### Verkorte titel

VIPAR

### Aandoening

dislocated, articular, distal radius, fracture, ORIF, plaster  
gedisloceerd, articulair, distale radius, fractuur, ORIF, gips

### Ondersteuning

**Primaire sponsor:** Academic Medical Center, Amsterdam

**Overige ondersteuning:** Self-financing

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

PRWE

# Toelichting onderzoek

## Achtergrond van het onderzoek

There is no consensus about the best treatment for patients with displaced complete articular distal radius fractures (AO type C fractures). Despite this lack of consensus and the lack of available literature on comparative data to guide treatment for this patient population, operative treatment with plate fixation has gained popularity. The aim of our study is to compare the functional outcome of open reduction and plate fixation with closed reduction and plaster immobilisation in adult patients (18-65 years) with displaced complete articular distal radius fractures.

## Doel van het onderzoek

Open reduction and internal plate fixation has a better functional outcome compared to closed reduction and plaster immobilisation.

## Onderzoeksopzet

1 week, 2/3 weeks, 6 weeks, 3 months, 6 months, 12 months

## Onderzoeksproduct en/of interventie

Open reduction and internal plate fixation versus plaster immobilisation

# Contactpersonen

## Publiek

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## Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients from 18 – 75 years
- AO type C displaced distal radius fracture, as classified on lateral, posterior anterior and lateral carporadial radiographs/CT-scan by a radiologist or trauma surgeon
- Fracture displacement is defined by the AO foundation as 'fragments not perfectly anatomically aligned'. Acceptable closed reduction obtained immediately after admission to the Emergency Department (<12hrs)

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with impaired wrist function prior to injury due to arthrosis/neurological disorders of the upper limb
- Open distal radius fractures
- Multiple trauma patients (Injury Severity Score (ISS)  $\geq 16$ )
- Other fractures of the affected extremity (except from ulnar styloid process)
- Fracture of other wrist
- Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician
- Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget's disease, renal osteodystrophy, osteomalacia)
- 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          |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Actieve controle groep  |

## Deelname

|                         |                       |
|-------------------------|-----------------------|
| Nederland               |                       |
| Status:                 | Werving gestopt       |
| (Verwachte) startdatum: | 19-06-2015            |
| Aantal proefpersonen:   | 90                    |
| Type:                   | Werkelijke startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 03-12-2014       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45181  
Bron: ToetsingOnline  
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL4777         |
| NTR-old  | NTR4915        |
| CCMO     | NL51544.018.14 |
| OMON     | NL-OMON45181   |

## Resultaten