

# Closed Reduction vs ORIF vs Non-Operative Study of intra-articular calcaneal fractures.

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Percutaneous, ORIF and conservative treated of displaced intra-articular calcaneal fractures have a similar outcome as measured with the AOFAS (American Orthopaedic Foot and Ankle Society) score.

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

## Samenvatting

### ID

NL-OMON27035

### Bron

Nationaal Trial Register

### Verkorte titel

CRONOS

### Ondersteuning

**Primaire sponsor:** -

**Overige ondersteuning:** Association Internationale pour L'Ostéosynthèse Dynamique (A.I.O.D.)

### Onderzoeksproduct en/of interventie

### Uitkomstmatten

#### Primaire uitkomstmatten

The primary outcome measure is the AOFAS score.

# Toelichting onderzoek

## Achtergrond van het onderzoek

Calcaneal fractures are a disabling injury and optimal treatment has yet to be determined. Three meta-analyses<sup>1-3</sup> on four RCT's, one prospective cohort study and three retrospective studies showed a trend towards overall improved outcome in patients treated with Open Reduction and Internal Fixation (ORIF), but most studies were clearly powered for specific outcomes and used non-comparable outcome scores.

The outcome after percutaneous treatment has not been studied in a randomised trial. Considering the above there is a need for a level-2 study comparing the different treatment modalities of ORIF, percutaneous treatment and conservative treatment, which is adequately powered to the most cited disease-specific outcome score: the American Orthopaedic Foot and Ankle Society Hindfoot Score (AOFAS).

This study aims to demonstrate a clinically significant difference of 20 points using the most cited and clinically relevant American Orthopedic Foot and Ankle Society hindfoot score (total 100 points) after 2 and 5 years.

ORIF, percutaneous reduction and fixation and conservatively treated patients will be compared in an adequately powered, multicenter randomized controlled trial with 3 treatment arms. Clinical outcome will be measured using the AOFAS score, standard physical exam and radiographic criteria after 2 and 5 years.

## Doeleind van het onderzoek

Percutaneous, ORIF and conservative treated of displaced intra-articular calcaneal fractures have a similar outcome as measured with the AOFAS (American Orthopaedic Foot and Ankle Society) score.

## Onderzoeksproduct en/of interventie

This study will randomise between: 1. the percutaneous, distraction, technique according to Forgon and Zadravec, 2. Open Reduction and Internal Fixation via a lateral approach, and 3. conservative treatment.

## Contactpersonen

## Publiek

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## **Wetenschappelijk**

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## **Deelname eisen**

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

1. All patients, with a displaced intra-articular calcaneal fracture;
2. Between 18 and 70 years old;
3. Compos mentis;
4. Living in the Netherlands;
5. Giving informed consent.

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

1. A fracture older than 14 days;
2. Grade III open fractures (Gustilo);
3. Patients with chronic substance abuse;
4. Homeless;
5. Non-ambulant patients;
6. ASA IV-V;
7. Participation in an other study.

## **Onderzoeksopzet**

## Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

## Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	150
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	07-06-2006
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	NL637
NTR-old	NTR697

**Register**

Ander register  
ISRCTN

**ID**

: N/A  
ISRCTN67665340

## Resultaten

### **Samenvatting resultaten**

1. AO-Publishing: Intraarticular calcaneal fractures; operative management. Orthop trauma dir, 2(1): 9-16, 2004.
2. Bridgman, S. A.; Dunn, K. M.; McBride, D. J.; and Richards, P. J.: Interventions for treating calcaneal fractures. Cochrane Database Syst Rev, (2): CD001161, 2000.
3. Randle, J. A.; Kreder, H. J.; Stephen, D.; Williams, J.; Jaglal, S.; and Hu, R.: Should calcaneal fractures be treated surgically? A meta-analysis. Clin Orthop, (377): 217-27, 2000.