

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

Gepubliceerd: 07-06-2006 Laatste bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON27035

Bron

NTR

Verkorte titel

CRONOS

Ondersteuning

Primaire sponsor: -

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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-analyses¹⁻³ 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 Orthopaedic 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.

Doel 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 Zadavec, 2. Open Reduction and Internal Fixation via a lateral approach, and 3. conservative treatment.

Contactpersonen

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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:	Geneesmiddel

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.