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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27035

Source NTR

Brief title CRONOS

Sponsors and support

Primary sponsor: -**Source(s) of monetary or material Support:** Association Internationale pour L'Ostéosynthèse Dynamique (A.I.O.D.)

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the AOFAS score.

Secondary outcome

Secondary outcome measures are the number of complications (infectious, osseous and osteosynthetic), returning to work, patient satisfaction (VAS) and quality of life (SF36) and the

1 - Closed Reduction vs ORIF vs Non-Operative Study of intra-articular calcaneal fra ... 3-05-2025

Study description

Background summary

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 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.

Study objective

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.

Intervention

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

Contacts

Public

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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. Partcipation in an other study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-07-2006
Enrollment:	150
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	07-06-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL637
NTR-old	NTR697

4 - Closed Reduction vs ORIF vs Non-Operative Study of intra-articular calcaneal fra ... 3-05-2025

Register	
Other	
ISRCTN	

ID : N/A ISRCTN67665340

Study results

Summary results

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.