Closed Reduction versus Open reduction and internal fixation versus Non-Operative Study of intra-articular calcaneal fractures

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/07/2006		☐ Protocol		
Registration date 21/07/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
08/01/2021	Injury, Occupational Diseases, Poisoning			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Protocol serial number

NL637, NTR697

Study information

Scientific Title

Closed Reduction versus Open reduction and internal fixation versus Non-Operative Study of intra-articular calcaneal fractures

Acronym

CRONOS

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Displaced intra-articular calcaneal fractures (Sanders type II-IV)

Interventions

Patients will be randomised into one of the following groups:

- 1. The percutaneous, distraction, technique according to Forgon and Zadravecz
- 2. Open reduction and internal fixation via a lateral approach
- 3. Conservative treatment

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome measure is the American Orthopaedic Foot and Ankle Society (AOFAS) score

Key secondary outcome(s))

- 1. Number of complications (infectious, osseous and osteosynthetic)
- 2. Return to work
- 3. Patient satisfaction (visual analogue scale [VAS])

- 4. Quality of life (short-form 36 questionnaire [SF36])
- 5. The need for a secondary arthrodesis

Completion date

01/07/2013

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Total final enrolment

169

Key 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. American Society of Anesthesiologists (ASA) IV-V
- 7. Partcipation in another study

Date of first enrolment

01/07/2006

Date of final enrolment

01/07/2013

Locations

Countries of recruitment

Netherlands

Study participating centre
University Medical Center Rotterdam
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation

Erasmus Medical Center, Department of Surgery (The Netherlands)

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Research organisation

Funder Name

International Association for Dynamic Osteosynthesis (Association Internationale pour L'Ostéosynthèse Dynamique) (A.I.O.D.)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014	08/01/2021	Yes	No

Study website Study website 11/11/2025 11/11/2025 No Yes