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

Submission date	Recruitment status
21/07/2006	No longer recruiting
Registration date	**Overall study status**
21/07/2006	Completed
Last Edited	**Condition category**
08/01/2021	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Randomised controlled trial

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
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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