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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

Study website
http://www.calcaneus.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/07/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
P.O.Box 2040
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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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