

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

Submission date

21/07/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

21/07/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/01/2021

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.calcanus.nl>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Zadavec
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. Participation 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

Rotterdam

Netherlands

3000 CA

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