Permissive Weight Bearing in Displaced Intra-Articular Calcaneal Fractures

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Evidence showing which aftertreatment protocol is best for both fracture healing and functional outcomes for patients with Displaced Intra-Articular Calcaneal Fractures (DIACFs) is lacking. This study has the aim to answer the question whether...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56739

Source
ToetsingOnline

Brief title
The PIONEER Study

Condition

- Bone and joint therapeutic procedures

Synonym
calcaneal fractures, heel bone fractures

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Calcaneal Fractures, Permissive Weight Bearing, Rehabilitation, Trauma patients

Outcome measures

Primary outcome

Primary objective is:

- Is functional outcome in PWB in surgically treated patients with DIACFs non-inferior to RWB after 6 months, as defined by the American Orthopaedic Foot & Ankle Society (AOFAS) Score?

Hypothesis 1: functional outcome, as defined by the AOFAS Score, for surgically treated patients with DIACFs following the PWB protocol is non-inferior compared to patients who followed the RWB protocol after 6 months.

Secondary outcome

- Are there differences in self-reported function in surgically treated patients with DIACFs following the PWB protocol compared to patients following the RWB protocol after 6 months?
- Are there differences in Health-Related Quality of Life (HRQoL) assessed by EuroQol-5D-5L in surgically treated patients with DIACFs following the PWB protocol compared to patients following the RWB protocol after 6 months?
- Is there a difference between the pre-operative and early post-operative Böhlers angle between surgically treated patients with DIACFs following the PWB or RWB protocol? Is there a difference between the early post-operative Böhlers angle and the Böhlers angle at 6 months post-operatively between surgically

treated patients with DIACFs following the PWB or RWB protocol? Is there a difference in the the posterior facet joint alignment (step-off and gap) when compared at 6 months between surgically treated patients with DIACFs following the PWB or RWB protocol?

- Is the PWB protocol cost-effective in surgically treated patients with DIACFs compared to RWB?
- Is there a difference in the occurrence of complications after 6 months between surgically treated patients with DIACFs following the PWB or RWB protocol?

Hypothesis 2: patients with DIACFs following the PWB protocol will have better self-reported function as defined by the Maryland Foot Score (MFS) than patients who followed the RWB protocol after 6 months.

Hypothesis 3: patients with DIACFs following the PWB will have an improved HRQoL defined by the EuroQoL 5-Dimension 5-Level (EQ-5D) than patients who followed the RWB protocol after 6 months.

Hypothesis 4: patients with DIACFs following the PWB will have no radiographically differences in comparison to patients following the RWB protocol when the intra-articular step-off (in mm) and gap (in mm) of the posterior facet and the Böhlers angle (in degrees) is compared between 6 months and directly post-operatively.

Hypothesis 5: health care and societal perspective, aftertreatment following PWB will be cost-effective in surgically treated patients with DIACFs as defined by the Medical Consumption Questionnaire (iMCQ) and the Productivity Cost Questionnaire (iPCQ), and QALYs using the EQ-5D, compared to patients who followed the RWB protocol, after 6 months.

Hypothesis 6: the complication rate (see *6. Methods* for complications) is equal or lower in patients with DIACFs following the PWB compared to patients following the RWB protocol after 6 months.

Study description

Background summary

Of all fractures, 1-2% involve the calcaneus. Often surgical treatment is needed. Even after successful treatment it requires long rehabilitation with major impact on daily life and socio-economic aspects. Anatomic surgical restoration does not prevent gait disturbances or persistent foot pain. Adequate rehabilitation is mandatory to maximize foot stability.

Study objective

Evidence showing which aftertreatment protocol is best for both fracture healing and functional outcomes for patients with Displaced Intra-Articular Calcaneal Fractures (DIACFs) is lacking. This study has the aim to answer the question whether functional outcome in surgically treated patients with DIACFs with aftertreatment following the Permissive Weight Bearing protocol (PWB) is non-inferior compared to Restricted Weight Bearing (RWB), after 6 months measured with the American Orthopaedic Foot & Ankle Society (AOFAS) Score. Furthermore, this study hypothesizes that surgically treated patients with DIACFs following the PWB protocol will have a better self-reported function and a better health-related quality of life (HRQoL) compared to patients who followed the RWB protocol. The hypothesis is that there will be lower costs without any radiographic differences for surgically treated (irrespective of the used surgical technique) patients with DIACFs following a PWB protocol comparing to the current AO (Arbeitsgemeinschaft für Osteosynthesefragen)

standard care: the RWB protocol.

Study design

Multi-center randomized controlled trial

Intervention

The PWB protocol allows earlier post-operative permissive weight bearing, where progression of weight bearing is guided by the subjective experience (for example: pain, weight bearing tolerance) of the patient and the clinical expertise of the treating physician and therapist. Patients allocated to the PWB protocol start weight bearing after wound healing is achieved (approximately two weeks after the operation). Consequently, patients are stimulated to bear as much weight as tolerated by pain and comfort. Treatment will take place according to the PROMETHEUS protocol (see J.).

Study burden and risks

The PWB protocol aims to restore weight bearing faster than RWB protocol in DIACFs. Early postoperative weight bearing poses the risk of increased complications, such as secondary displacement of the fracture or failure of fracture fixation. Previous analysis of this protocol in other lower extremity fractures has shown a safe complication rate, although data from prospective randomized trials in calcaneus fractures is lacking. Follow-up is standardized according to current trauma guidelines, namely at time points 2, 6, 12 weeks and 6 months. The radiation exposure for both groups will differ from standard care (one extra CT scan of the foot will be made). Therefore, the burden for participants is considered minimal, with no significant health risks.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Surgically treated trauma patients with isolated unilateral DIACFs, less than 6 weeks after trauma, Sanders type II-IV
• Isolated unilateral calcaneal fractures
• Age between 18 and 67 years old (labor force)
• Being able to understand the questionnaires and measurement instructions
• Indication for open/closed reduction and internal fixation
• Written Informed Consent

Exclusion criteria

• Acute or existing amputation (upper limb, lower limb, feet)
• Open calcaneal fractures (excluding medial wound without compromising surgical approach)
• Bilateral fractures of the lower extremities
• Unable to comply to the PWB protocol due to pre-existing conditions of the arms and legs (e.g. unable to use crotches due to hemiparalysis)
• Severe non-fracture related comorbidity of the lower extremity
• Pre-existent immobility (loss of muscle function of one or both legs)
• Dependent in activities of daily living (e.g. due to dementia, Alzheimer, New York Heart Association class IV angina and heart failure, oxygen-dependent chronic obstructive pulmonary disease)
• Rheumatoid arthritis of the lower extremities
• Severe psychiatric comorbidities that lead to inability to comply with the treatment protocol
• Pathologic fractures (metastasis, secondary osteoporosis)
• Peripheral neuropathy and/or diabetes
• Alcohol- or drug abuse preventing adequate follow-up

• Primary indication for arthrodesis subtalar joint
• Two or more fractures of the upper and/or lower extremities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-06-2024
Enrollment:	115
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-09-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-12-2024

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL83269.068.23