Retrospective evaluation of surgically treated unstable type C ankle fractures: long term functional and radiological outcomes.

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To evaluate the long term functional and radiological effects of surgical treatment of Weber type C (AO 44-C1/2/3) fibular fractures

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON57050

Source
ToetsingOnline

Brief title
RESULT study

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
broken ankle, type C fibula fracture

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum

Source(s) of monetary or material Support: aanvraag lokaal wetenschapsfonds

Intervention

Keyword: Ankle fracture, osteoarthritis, trimalleolar ankle fracture, type C ankle fracture

Outcome measures

Primary outcome

Functional outcome of the ankle, assessed using the validated completely patient reported version of the PROM American Orthopaedic Foot and Ankle Score (PR-AOFAS), which provides a score ranging from 0 (worst possible functional outcome) to 100 0 (best possible functional outcome).

Secondary outcome

- Functional outcome measured with the PROMIS Physical Function short form 8b.

- Pain measured with a visual analogue scale (VAS)

- The extent of osteoarthritis, assessed on anteroposterior, lateral and mortise view ra-diopgraph, using the Kellgren and Lawrence score for osteoarthritis, modified by Ki-jowski et al.

- Complications including secondary interventions/reoperations

Study description

Background summary

Despite the prominent position of ankle fractures in the daily practice of orthopaedic trauma surgery, relatively little is known about the long-term prognosis of operatively treated Weber C ankle fractures. It is suggested that Weber C fractures have a clinically less satisfactory outcome, however, large clinical studies evaluating long-term outcomes are lacking. The aim of this study is to evaluate the long-term functional and radiological outcome of surgically treated Weber C ankle fractures.

Study objective

To evaluate the long term functional and radiological effects of surgical treatment of Weber type C (AO 44-C1/2/3) fibular fractures

Study design

Multicenter retrospective cohort study.

Study burden and risks

Participants of this study will not benefit directly by participating, other than the opportunity to receive extra information if they experience any problems or have any questions regarding their injury. The extra radiation exposure of the X-rays poses a negligible risk since is it represents about 1/100th of the background radiation. The one-time visit to the outpatient clinic is considered a burden for the patients because it takes time. Filling out the two short questionnaires is considered to pose a minimal burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Males or females aged 18 to 75 at the time of trauma and who are competent and capable to make medical decisions.
- Operated due to a Weber C fracture (AO type 44-C1/2/3) between January 1st 2012 and June 1st 2016.
- Sufficient understanding of the Dutch or English language in order to independently understand the patient information including informed consent and complete the follow-up questionnaires.
- Provision of informed consent by the patient.

Exclusion criteria

- Unable to follow up (e.g. deceased, living abroad)
- Pathological fractures
- Multi-extremity fractures or other injuries at time of trauma.
- History of ankle fracture on the same ankle prior to the operation.
- Impaired function of the operated ankle prior to the operation.
- Patients with decreased use of the ankle due to disability of other cause
- Operated on prior to enrolment of the electronic hospital information system (no availability of digital initial trauma radiographs).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	14-10-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-02-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL87654.058.24