Treatment of the fifth metatarsal shaft fractures: a randomised controlled trial.

Published: 18-07-2022
Last updated: 06-04-2024

The main objective is to determine function/clinical outcome, measured by the NRS-11 score for pain, 3 months after intervention and compare this between the surgery and conservative group. Secondary objectives are functional outcome as measured by…

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

Summary

ID

NL-OMON51375

Source
ToetsingOnline

Brief title
FOOT (Fifth metatarsal Orthopedic Outcome Trial)

Condition

- Bone and joint therapeutic procedures

Synonym
fifth metatarsal shaft fractures, fractures of the lesser toe

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: mogelijk door het Innovatie en Wetenschapsfonds Isala

Intervention

Keyword: Fifth Metatarsal, Fracture, RCT, Shaft

Outcome measures

Primary outcome

The main study endpoint is difference in NRS-11 score for pain between the two groups at three months. This is a patient reported rating scale, resulting in a score ranging from 0-10 where 10 is the worst pain ever experienced.

Secondary outcome

Impact on daily living will be measured by

* Return to work

* Return to normal footwear

Impact on fracture healing will be measured by

* Malunion of the fracture

* Non-union of the fracture

* Complication rate

Functional outcome will be measured by the questionnaires

* FAAM

* PROMIS

* AOFAS LTS

* NRS-11 measured across the different timepoints of the follow up (6 weeks. 3, 6 and 12 months)

Study description

Background summary

Fractures of the shaft of the fifth metatarsal often occur after foot distortion. Yet there is very little evidence available regarding the optimal treatment. Currently the most common treatment is prolonged cast immobilization. Operative treatment has been reported as an alternative and could promote early recovery. No comparative study has been published regarding optimal treatment.

Study objective

The main objective is to determine function/clinical outcome, measured by the NRS-11 score for pain, 3 months after intervention and compare this between the surgery and conservative group. Secondary objectives are functional outcome as measured by FAAM score, AOFAS LTS and PROMIS Mobility and Pain interference. Furthermore quality and duration of fracture healing will be compared between groups. The impact on daily life will be compared as measured by duration of return to work and normal footwear.

Study design

Randomized controlled clinical intervention trial

Intervention

The intervention group is offered surgical treatment of the shaft fracture of the fifth metatarsal bone with ORIF. Depending on the type of shaft fracture this will be either lag screw fixation or plate fixation. After surgery a period of cast immobilization with gradual increase of weight bearing will commence.

The control group (conservative treatment), will receive a period of cast immobilization, with a gradual increase in weight bearing by protocol.

Study burden and risks

The intervention group will undergo surgery as described in the section ''intervention''
The intervention group is exposed to the common risks associated with the surgical procedure such as: Infection of the incision site or osteosynthesis material, local paraesthesia and the risks of anaesthesia. Both groups are at risk of developing deep venous thrombosis. The control group is at risk of complex regional pain syndrome. In both groups risks are all low to negligible.

The benefit for the intervention group can be less persisting pain and earlier, or at least equally fast, functional recovery compared to the control group. These benefits are expected to be present in the vast majority of the group. Thus the benefits are deemed to outweigh the risks.

The participants will have to fill out questionnaires at six weeks, three, six and 12 months after inclusion. These questionnaires will take 20 minutes max in total. The questions will not concern any burdensome topics such as sexuality or very personal information.

If no benefit is seen the clinical equipoise can be resolved and current treatment will be continued, preventing further exposure to the risks of surgical treatment.

Contacts

Public
Isala Klinieken

Dr. Van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

Dr. Van Heesweg 2
Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older at the time of study entry
- Informed consent
- Competent to participate in follow up and fill out questionnaires
- Dislocated (1mm or more on plain radiography) fracture of the shaft, distal from zone 3, of the fifth metatarsal according to the Orthopedic Trauma Association (OTA) classification 87.5.3 A-C

Exclusion criteria

- Open fracture
- Proximal fifth metatarsal fracture, Jones fracture
- Clinically significant or symptomatic vascular or neurologic pathology on the ipsilateral leg
- Former surgery or history of development disorder of the contralateral fifth metatarsal
- Multiple fractured metatarsals in the affected foot
- Medical history of Rheumatoid Arthritis
- Unable to undergo surgical procedure

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:	Pending
Start date (anticipated):	01-09-2022
Enrollment:	64

Type:	Anticipated

Ethics review

Approved WMO Date:	18-07-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL80748.075.22
Other	volgt