# TREATMENT OF FRACTURES OF THE DISTAL SHAFT OF THE FIFTH METATARSAL: A RANDOMISED CONTROLLED TRIAL

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Primary objective:Difference in AOFAS lesser increase scale after 3 months.Secondary objectives:VAS pain scoresFracture Consolidation PeriodDelayed unionLength MT-V measured at contralateral MT-V, malunionQuestionnaire FAAM

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Fractures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36727

**Source**
ToetsingOnline

**Brief title**
FOOT
(Fifth metatarsal Orthopaedic Outcome Trial)

### Condition

- Fractures
- Bone and joint therapeutic procedures

**Synonym**
fifth os metatarsal shaft fractures. fractures of lesser toe

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Isala Klinieken
**Source(s) of monetary or material Support:** nvt

## Intervention

**Keyword:** conservative, distal shaft fracture, fifth os metatarsal, operative

## Outcome measures

### Primary outcome

Difference in functional outcome using AOFAS lesser toe scale

### Secondary outcome

Difference in fracture consolidation period in both groups

Difference in VAS scores

The level of delayed and non-union in fracture

Registration of complications

FAAM score

# Study description

### Background summary

The treatment of fractures of the shaft of the fifth metatarsal (MT-V) is in most cases a conservative treatment. Only in angulated and/or dislocated fractures a surgical treatment is indicated. The surgical treatment is open reposition and internal fixation. Literature contains only one retrospective study, includes 35 patients of whom 31 were treated conservatively. The four operated patients were treated with K-wire fixation.
There is no good prospective randomized study of the treatment of fifth metatarsal mid-shaft fractures. We want to perform a prospective randomized trial in the outcome of conservative versus operative treatment of fifth metatarsal mid-shaft fractures.

### Study objective

Primary objective:
Difference in AOFAS lesser increase scale after 3 months.

Secondary objectives:
VAS pain scores
Fracture Consolidation Period
Delayed union
Length MT-V measured at contralateral MT-V, malunion
Questionnaire FAAM

## Study design

This is a prospective randomized trial. Patients with a fifth metatarsal mid-shaft fracture will be included. At Inclusion, with informed consent, standard X-rays are made. Questionnaires will be filled in. Randomisation for treatment. This is either the conservative treatment or surgical treatment. Conservative treatment consists of 2 weeks LU-splint and 4 weeks forefoot relieving shoe.
The surgical treatment is open reduction and internal fixation (ORIF)., followed with 2 weeks LU-splint and 4 weeks forefoot relieving shoe.
During the treatment period the patient will have a "pain diary", consisting that each week an average pain VAS score is scored.
After the first treatment period of 6 weeks questionnaires filled in and radiographs are taken, including the contralateral foot to evaluate MT-V length.
Follow-up after 3 months, 6 months and 1 year.
The maximum follow-up is 1 year.

## Intervention

Conservative treatment consists of 2 weeks LU-splint and 4 weeks forefoot relieving shoe.
The surgical treatment is open reduction and internal fixation (ORIF)., followed with 2 weeks LU-splint and 4 weeks forefoot relieving shoe.

## Study burden and risks

The extent of the burden in both groups:
6 times outpatient visit with questionnaires and Xrays
first 6 weeks (during treatment), a weekly VAS is scored

Extent of the burden in the surgical group:
Admission in hospital
The operation itself

Risks:

Surgical risks, such as a wound infection

## 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

Patient with dislocated distal shaft fifth metatarsal fracture
above 18 years-old
Informed consent

### Exclusion criteria

clinical relevant vascular and/or neurological disorders

previous foot surgery
Rheumatoid arthritis
Unable to undergo surgery
Not being able to visit the clinic

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-07-2011 |
| Enrollment: | 40 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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|---|---|
| Date: | 13-10-2011 |
| Application type: | First submission |
| Review commission: | METC Isala Klinieken (Zwolle) |

# 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 | NL34571.075.11 |