# The effect of concentrated Blood and Bone Marrow Aspirate (cB+cBMA) in operative treatment of fifth metatarsal stress fractures

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To study the effect of using cB+cBMA in the operative treatment of MT-V stress fractures on the time to fracture healing.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Bone and joint therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON38972

**Source**
ToetsingOnline

**Brief title**
cB+cBMA in MT-V stress fractures

### Condition

- Bone and joint therapeutic procedures

**Synonym**
fatique fracture, stress bone reaction, stress fracture

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Biomet,Onafhankelijke fondsen en een

bedrijf: Biomet

## Intervention

**Keyword:** bonemarrow, operative, stress fractures, treatment

## Outcome measures

### Primary outcome

Radiological time to fracture union (in weeks)

### Secondary outcome

- time to clinical union (weeks)

- complication rate and safety

- patient function and satisfaction (FAAM, AOFAS, SF36)

- analysis of the composition of the aspirate (CD 34, CD 45, CD 105, CD 146, CD

90, CD 271, CFU-F assay, absoluut aantal cellen, 7 AAD, qRT-PCR analyse)

- analysis of the bone biopsions

- eventually adjust the research protocol for the RCT phase (phase II)

# Study description

### Background summary

Fifth metatarsal (MT-V) stress fractures are ill-famed for their long time to union. Even the current gold standard, being operative treatment, does not present optimal results with a mean time to fracture union of grossly 18 weeks. The aim of the current trial is to study if it is possible to shorten this time to fracture union after operative treatment of MT-Vstress fractures with use of concentrated blood and bone marrow aspirate (cB+cBMA).

### Study objective

To study the effect of using cB+cBMA in the operative treatment of MT-V stress fractures on the time to fracture healing.

### Study design

This study will be a patient and evaluator blinded randomized, controlled trial. A standard operative treatment (no supplementation with cB+cBMA) will be used as control group.

### Intervention

Experienced foot/ankle or trauma orthopedic surgeons will perform the surgeries. The surgery will be internal fixation and bone graft, with use of an intramedullary lag screw and an internal bone graft from the decortication (a little piece is used as a biopsy for further research) along the fracture lines.
From all patients a cB+cBMA will be obtained. This will be used for laboratory analysis and will be added to the fracture site together with the internal bone graft in the intervention group.
The cB+cBMA will be obtained through needle aspiration from patient*s own iliac crest and utilizing MarrowStim Concentration System (Biomet Biologics). This device will concentrate the aspirate by centrifuge and filtering.

### Study burden and risks

We expect that the intervention risk is low.
The bone marrow will be obtained during the operation, while patients are anesthetized; they do not feel it. The centrifugation and filtration happen when the surgeon starts with the open reduction and internal fixation of the MT-V fracture, so no extended OR time (only 5 minutes) is expected.
Possible known risk of collecting bone marrow from the iliac crest are hematoma, (temporary) hyper/hypoesthesia, infection, and pain. Risk of adding the cBMA to the fracture site is local pain.
Furthermore surgery of MT-V fractures can lead to common complications of surgery like local hematoma, neurological failure and infection. It is also possible to not reduce the local pain. Possibly surgery cannot prevent delayed- or non-union of the fracture. Surgery is considered the gold standard of treatment for these fractures at the moment.

## 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

skeletally mature
stress fracture of fifth metatarsal on X-ray

## Exclusion criteria

*Expected non-compliance (patients who are unable to fill out questionnaires and cannot have them filled out)
*Patients participating in another clinical trial
*Patients suffering from auto-immune disease
*Patients receiving biologicals, prednisolon or some kind of chemotherapy < 1 year
*Concomitant painful or disabling disease of the lower limb
*No informed consent
*Pregnant and nursing women
*Active malignancy

# Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |

**Primary purpose:** Treatment

### Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 50 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 23-12-2013 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 19971
Source: NTR
Title:

### In other registers

| Register | ID |
| --- | --- |
| CCMO | NL44856.018.13 |
| OMON | NL-OMON19971 |