# Chevron osteotomy for the treatment of hallux valgus - Effectiveness of postoperative immobilisation by a plaster cast or walking boot

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Primary aim of the study: to compare the preservation of the correction of hallux valgus angle by means of a Chevron osteotomy with postoperative immobilisation by means of a plaster cast or a removable walking boot, one year following surgery....

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bone disorders (excl congenital and fractures) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON38594

**Source**
ToetsingOnline

**Brief title**
Chevron osteotomy: immobilisation by cast or walking boot?

### Condition

- Bone disorders (excl congenital and fractures)

**Synonym**
deformity of the big toe, hallux valgus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Martini Ziekenhuis

**Source(s) of monetary or material Support:** Geen additionele financiering.

## Intervention

**Keyword:** Chevron osteotomy, Hallux valgus, immobilisation, physical functioning, plantar pressure

## Outcome measures

### Primary outcome

Primary study parameter is the proportion patients with a loss of more than 5 degrees of the correction of the hallux valgus angle (HVA), one year following surgery.

The HVA is measured at standard weigtbearing X-rays of the foot by means of a reliable measurement protocol. These X-rays are part of the standard clinical follow-up after Chevron osteotomy. They are made preoperatively, and one day, 6 weeks, 6 and 12 months postoperatively. A loss of more than 5 degrees of the correction of the hallux valgus angle is considered a clinically relevant loss.

### Secondary outcome

- Difference in (the course of regression of the) HVA and Intermetatarsal 1 and 2 angle (IMA)

- Plantar pressure:

- peak pressure of eight regions of the forefoot

Plantar pressure during walking will be assessed preoperatively and 3, 6 and 12 months postoperatively. Since the postoperative immobilisation will take 6

weeks, the first postoperative measurement will take place at 3 months following surgery. Plantar pressure will be measured by means of insoles which contain pressure sensors, the Pedar Insole system® (Novel, München, Duitsland). The Pedar Insole system is a wireless system, containing insoles that are connected to a data-receiver that is carried on the waist. To exclude variation in results because of differences in shoes, standardizes shoes will be used for the measurements.

- Physical functioning
- Health-related quality of life.

Physical functioning and health-related quality of life will be assessed by means of questionnaires. These questionnaires will be assessed preoperatively, and 6 weeks, 3, 6 and 12 months postoperatively. Physical functioning will be measured by means of the Foot Function Index (FFI). The FFI consists of 23 items, divided into 3 subscales. Health-related quality of life will be measured by means of the EQ-5D, consisting of 5 questions.

## Study description

**Background summary**

Deformity of the big toe is a common orthopedic problem, and 33% of the general Dutch population has a hallux valgus. This deformity of the big toe can ultimately lead to pain and gait deviations. A symptomatic hallux valgus is often treated surgically, to correct the anatomic deformity. The Chevron osteotomy is a much used surgical technique for this. Postoperative immobilisation can be done by means of a plaster cast or a removable walking boot. An advantage of the walking boot is that it is more comfortable compared to a plaster cast. However, it is unknown whether immobilisation by means of

the walking boot results in a remained correction of the hallux valgus. The hallux valgus correction might be better preserved by means of a plaster cast, because the reefed capsule gets a better chance for scarring in the by surgery obtained position. To date, there is a lack of studies in which the effectiveness of the two types of postoperative immobilisation following Chevron Osteotomy - a plaster cast or a removable walking boot - has been compared.

## Study objective

Primary aim of the study: to compare the preservation of the correction of hallux valgus angle by means of a Chevron osteotomy with postoperative immobilisation by means of a plaster cast or a removable walking boot, one year following surgery. Secondary aims are: to compare the effectiveness of the immobilisation by means of a plaster cast or a walking boot for the recovery of plantar pressure during walking, and recovery of physical functioning and quality of life.

## Study design

A prospective randomised controlled trial will be conducted. Two types of postoperative immobilisation following Chevron Osteotomy will be compared. The control group will receive postoperative immobilisation by means of a removable walking boot. The study group will receive postoperative immobilisation by means of a plaster cast. Measurements will take place preoperatively and 6 weeks, and 3, 6 and 12 months postoperatively. The study will be conducted at the Department of Orthopedic Surgery of the Martini Hospital Groningen.

## Intervention

The type of postoperative immobilisation will be determined by means of randomisation. The anesthetic and pain protocols will be standardized. Discharge criteria will also be the same in both study groups.

Treatment of the study group (Chevron osteotomy with postoperative immobilisation by means of a plaster cast):
Postoperative immobilisation will be performed by means of a (non-removable) plaster cast, for a period of six weeks. Only partial weigthbearing is allowed (only the heel). This plaster cast will be created by a master caster.

Treatment of the control group (Chevron osteotomy with postoperative immobilisation by means of a removable walking boot):
Postoperative immobilisation will be performed by mean of a removable walking boot, for a period of six weeks. Complete weightbearing is allowed. This walking boot will be created by an orthopedic shoemaker.

**Study burden and risks**

Since both types of postoperative immobilisation are usual care for the postoperative treatment of Chevron osteotomy, no additional risks are associated with participation of the study. No extra X-rays will be made, since the X-rays that are part of the clinical follow-up of Chevron osteotomy are used. No additional risks are associated with the plantar pressure measurements by means of the Insole system.

# 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

- at least 18 years old;

- mild symptomatic hallux valgus: intermetatarsal 1 and 2 angle (IMA) of <16 degrees, and a hallux valgus angle (HVA) of <30 degrees.

### Exclusion criteria

Patients with:
- Diabetes mellitus;
- Rheumatoid arthritis;
- Predison use.

## 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: | Other |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-08-2015 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 05-12-2013 |
| Application type: | First submission |
| Review commission: | RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden) |

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| Approved WMO Date: | 10-07-2014 |
| Application type: | Amendment |
| Review commission: | RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden) |

# 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 | NL46732.099.13 |
| Other | NTR15564 |