

# The effectiveness of two different valgus braces in the treatment of varus medial compartment osteoarthritis of the knee: a randomized clinical trial

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Our primary objective is to compare the short term (3 months follow-up) clinical and radiographic results of the Bledsoe Thruster Brace with the SofTec OA Brace in the management of patients with medial knee OA and a varus leg alignment.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34102

### Source

ToetsingOnline

### Brief title

Valgus bracing

### Condition

- Joint disorders

### Synonym

arthrosis of the knee, gonarthrosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Alysis Zorggroep

**Source(s) of monetary or material Support:** Bauerfeind Benelux B.V. (Waarderveldweg 1, 2031 BK, Haarlem, Nederland) ,Bauerfeind Benelux B.V. (Waarderveldweg 1;2031 BK;Haarlem;Nederland) en B&CO INC NV (Mutsaardstraat 47;9550 Herzele;België).,en B&CO INC NV (Mutsaardstraat 47, 9550 Herzele, België)

## Intervention

**Keyword:** "valgus bracing", "varus knee", osteoarthritis, unicompartmental

## Outcome measures

### Primary outcome

Difference in the VAS pain score at 3 months between the Bledsoe Thruster group and the SofTec OA Brace group.

### Secondary outcome

Visual Analogue Scale for pijn and satisfactio (VAS-pain, VAS-satisfaction), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the SF-12 and the 6-Minutes Walking Test at baseline, 2 weeks and 3 months.

Radiographs of varus leg alignment at baseline without brace and at 3 months with brace.

Patients need to keep a diary once a week during the 3 months of participation.

In this diary they record mean daily analgesics use, complications and compliance.

## Study description

### Background summary

Knee osteoarthritis (OA) is one of the most common joint disorders and is a major cause of knee pain and immobility. Treatment can be non-operative or operative. Operative treatment is not suitable for every patient, because of medical comorbidity, old age or other circumstances. In young patients it is desirable to delay primary arthroplasty. Osteoarthritis of the knee is more

located in the medial compartment. Patients with OA of the medial compartment also often have a varus alignment and the varus deformity causes an overload of the medial compartment with increasing symptoms during weight bearing. Malalignment increases risk for progression of knee OA. Valgus braces are designed to unload the medial compartment in order to decrease pain and improve function. Recent systematic reviews concluded that there is very limited evidence for the effectiveness of brace treatment for medial knee osteoarthritis, mainly because of lack of randomized clinical trials. More than 30 commercially available braces are produced nowadays, with all kind of different brace designs. To our knowledge no study has compared the effectiveness of two different kind of braces as treatment of medial knee OA in a randomized clinical trial.

## **Study objective**

Our primary objective is to compare the short term (3 months follow-up) clinical and radiographic results of the Bledsoe Thruster Brace with the SofTec OA Brace in the management of patients with medial knee OA and a varus leg alignment.

## **Study design**

A multicentre prospective parallel-group randomized clinical trial.

## **Intervention**

Intervention (if applicable): Trial arm 1: 3 month prescription of the Bledsoe Thruster Brace. Trial arm 2: 3 month prescription of the SofTec OA Brace.

## **Study burden and risks**

There are not many complication mentioned in the literature. Only minor skin irritations, skin deficits and blisters. The only other expected problem is a possible bad fit and discomfort of the brace. The extra burden associated with participation in this study are the Visual Analogue Scale pain and satisfaction, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the SF-12 and the 6-Minutes Walking Test at baseline, 2 weeks and 3 months and radiographs of varus leg alignment with brace at 3 months. Patients need to keep a diary once a week during the 3 months of participation.

# **Contacts**

## **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Patients with medial knee osteoarthritis (confirmed on X-ray (AP and lateral) using the Kellgren classification).

Medial knee pain.

Varus leg alignment (confirmed on X-ray).

Age between 18-70.

### **Exclusion criteria**

Insufficient command of the Dutch language.

The inability to apply brace because of physical or cognitive limitations.

Symptomatic back/hip/ankle/foot pathology (which makes improvement of pain, function, quality of life and satisfaction, by wearing a brace, impossible).

Other than osteoarthritis causing knee pain (like arthritis).

Pre-existing skin problems.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2010
Enrollment:	80
Type:	Actual

### Medical products/devices used

Generic name:	The Bledsoe Thruster Brace versus the Softec OA Brace
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	27-09-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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

Other	Het is aangemeld in het Nederlands Trial Register. We wachten nog op het registratienummer.
CCMO	NL32412.091.10