The effectiveness of a valgus brace in the treatment of varus medial compartment osteoarthritis of the knee: a randomized clinical trial

Published: 15-01-2019
Last updated: 12-04-2024

Our primary objective is to compare the short and medium term (up to 6 months) clinical results in pain and function of the Bauerfeind SecuTec OA brace with only conservative treatment (no brace) in the management of patients with medial knee OA and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON52722

Source
ToetsingOnline

Brief title
SecuTec OA brace versus no brace

Condition

- Joint disorders

Synonym
arthrosis of the knee, Gonarthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: Bauerfeind AG;Triebeser Strasse 16;D-07937 Zeulenroda-Triebes.

Intervention

Keyword: medial compartment, osteoarthritis, valgus bracing, varus knee

Outcome measures

Primary outcome

Difference in the VAS pain score at 6 months between the Bauerfeind SecuTec OA brace and controls receiving only conservative treatment.

Secondary outcome

Visual Analogue Scale 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, 3 and 6 months. Patients need to keep a diary once a week during the 6 months of participation (24 weeks). In the brace group, patients record their analgesic usage, physical therapy usage, compliance and adverse events. In the control group, analgesic usage and physical therapy usage are recorded. After the final 6-month measurement, patients from the intervention group (1) will be invited to undergo a 30-minute in-depth semi-structured interview focussing on their perceptions about the (use of the) brace.

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 (1, 2). 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 due to a higher revision rate in short and long term (3, 4). Osteoarthritis of the knee is most often located in the medial compartment (5). Patients with OA of the medial compartment also often have a varus alignment.The varus deformity causes an overload of the medial compartment with increasing symptoms during weight bearing. Malalignment increases risk for progression of knee OA (6-9). Valgus braces are designed to unload the medial compartment in order to decrease pain and improve function (1, 10, 11). In recent years there have been numerous studies focussing on the effectiveness of brace treatment for medial knee osteoarthritis. Despite numerous studies, recent (systematic) reviews conclude that there is still limited evidence of the effectiveness of brace treatment mainly because of poor methodology and the absence of large randomized controlled clinical trials (12, 13). Therefore, we propose a methodological sound randomized controlled clinical trial comparing the new Bauerfeind SecuTec OA brace to controls receiving only a standard of care conservative treatment (14).

Study objective

Our primary objective is to compare the short and medium term (up to 6 months) clinical results in pain and function of the Bauerfeind SecuTec OA brace with only conservative treatment (no brace) in the management of patients with medial knee OA and a varus leg malalignment.
Our secondary objective is to explore the intervention group patients* perceptions about the (use of the) Bauerfeind SecuTec OA brace in terms of activities, aesthetics, (dis)comfort/ergonomics, physical effects and usability.

Study design

A monocenter randomized controlled clinical trial.

Intervention

Group 1: 6 months prescription of the Bauerfeind SecuTec OA brace in combination with the standard conservative treatment containing of education and analgetics / physical therapy if needed.
Group 2: 6 months standard conservative treatment containing of education and analgesics / physical therapy if needed .

Study burden and risks

There are not many complications mentioned in the literature. Only minor skin irritations, skin deficits, blisters and discomfort from wearing 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, 3 months and 6 months follow-up. Additionally, patients are asked to fill out a diary once a week during the 6 months participation (usage of analgesics and physical therapy, brace compliance and complications).

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

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 40-70.

Exclusion criteria

Insufficient command of the Dutch language.
The inability to apply a 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.
OA confirmed Kellgren classification grade I or IV.
Systemic disease influencing the musculoskeletal system including among others rheumatoid arthritis, fibromyalgia and systemic lupus erythematosus.
Body mass index above 35.
Distinct patellofemoral osteoarthritis.
Intra-articular injection with glucocorticosteroids combined with analgesics within 3 months.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2019
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	SecuTec OA brace
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-01-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-11-2022
Application type:	Amendment
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
CCMO	NL66797.091.18