De effectiviteit van een kniebrace in de behandeling van artrose van de knie: een gerandomiseerde klinische studie.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20677

Source
NTR

Brief title
SecuTec OA brace versus no brace

Health condition

valgus bracing / valgus bracing
medial compartment / mediale compartiment
osteoarthritis / osteoarthitis
varus knee / varus knie

Sponsors and support

Primary sponsor: Bauerfeind AG
Triebeser Strasse 16
07937 Zeulenroda-Triebes
Germany
Source(s) of monetary or material Support: Bauerfeind AG
Triebeser Strasse 16
07937 Zeulenroda-Triebes
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Intervention

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.

Study description

Background summary

Background of the study:

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 due to a higher revision rate in short and long term. Osteoarthritis of the knee is most often located in the medial compartment. 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. Valgus braces are designed to unload the medial compartment in order to decrease pain and improve function. 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. 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.

Objective of the study:

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.

Study design:

A multicentre randomized controlled clinical trial.

Study population:

Patients diagnosed with medial knee OA and a varus malalignment, aged between 40 and 70 years.

Intervention (if applicable):

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 .

Primary study parameters/outcome of the study:

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

Secundary study parameters/outcome of the study (if applicable):

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

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).

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. Hypothese: The management with brace is superior

Study design

baseline, 2 weeks, 3 months, 6 months.

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 .

Contacts

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Eligibility criteria

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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-10-2018
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7242
NTR-old	NTR7441
Other	: ABRnr: 66797

Study results