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

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20677

Bron
NTR

Verkorte titel
SecuTec OA brace versus no brace

Aandoening

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

Ondersteuning

Primaire sponsor: Bauerfeind AG
Triebeser Strasse 16
07937 Zeulenroda-Triebes
Germany
Overige ondersteuning: Bauerfeind AG
Triebeser Strasse 16
07937 Zeulenroda-Triebes

Germany

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

baseline, 2 weeks, 3 months, 6 months.

Onderzoeksproduct en/of interventie

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 .

Contactpersonen

Publiek

Wagnerlaan 55
S. Grinsven, van
Arnhem 6800 TA
The Netherlands
+31 (0)88 0056366

Wetenschappelijk

Wagnerlaan 55
S. Grinsven, van
Arnhem 6800 TA
The Netherlands
+31 (0)88 0056366

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-10-2018
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7242
NTR-old	NTR7441

Register
Ander register

ID
: ABRnr: 66797

Resultaten