

Valgus bracing.

Gepubliceerd: 13-07-2010 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26399

Bron

NTR

Aandoening

Valgus bracing, unicompartmental osteoarthritis, varus knee, RCT

Ondersteuning

Primaire sponsor: Maatschap orthopaedie ziekenhuis Rijnstate

Overige ondersteuning: Bauerfeind Benelux B.V. (Softec OA Brace), Waarderveldweg 1, 2031 BK Haarlem, The Netherlands

B&Co INC NV (Bledsoe Thruster Brace), Mutsaardstraat 47, 9550 Herzele, Belgium

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

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. 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.

Doel van het onderzoek

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

Onderzoeksopzet

Baseline, 2 weeks and 3 months.

Onderzoeksproduct en/of interventie

Trial arm 1: 3 months prescription of the Bledsoe Thruster Brace.

Trial arm 2: 3 months prescription of the SofTec OA Brace.

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)

1. Patients with medial knee osteoarthritis (confirmed on x-ray (AP and lateral) using the Kellgren classification);
2. Medial knee pain;
3. Varus leg alignment (confirmed on X-ray);
4. Age between 18-70.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Insufficient command of the Dutch language;
2. The inability to apply brace because of physical or cognitive limitations;
3. Symptomatic back/hip/ankle/foot pathology (which makes improvement of pain, function, quality of life and satisfaction, by wearing a brace, impossible);
4. Other than osteoarthritis causing knee pain (like arthritis);
5. Pre-existing skin problems.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	13-07-2010
Soort:	Eerste indiening

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	NL2322
NTR-old	NTR2428
Ander register	CCMO : 2010/200
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A