Orthosis for treatment of Knee Osteoarthritis

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON23870

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

osteoarthritis, gonartrose

Ondersteuning

Primaire sponsor: Department of Orthopedics, Martini Hospital Groningen
Overige ondersteuning: D.H. Heijne stichting
OIM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) (Bellamy et al. 1988), an osteoarthritis specific questionnaire for pain, stiffness and

functioning between pre-intervention and after 24 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Recent studies have shown that regeneration might occur in osteoarthritis of the knee by using a joint distraction procedure in combination with joint mobility. This procedure provides both time and opportunity for self-healing by preventing mechanical loading and allowing nutrition transport to the cartilage. The current invasive method has a high potential for infection. We hypothesize, that the use of a knee orthosis that allows knee mobility but unloads the joint, will result in reduction of symptoms and regeneration of an osteoarthritic knee joint. The aim of this study is to test a load-reducing leg orthosis for treatment of osteoarthritis on functioning, pain, severity of knee osteoarthritis and safety of the device.

Doel van het onderzoek

The hypothesis is that this load-reducing orthosis will result in reduction of symptoms and regeneration of cartilage in an osteoarthritic knee joint.

Onderzoeksopzet

T0: start orthosis use, visit orthopedic surgeon, questionnaires, X-ray and MRI.

T1: 2 months (end using orthosis), questionnaires and X-ray

T2: 6 months, visit orthopedic surgeon, questionnaires and X-rays.

T3: 12 months, visit orthopedic surgeon, questionnaires, X-rays and MRI.

T4: 18 months, questionnaires and X-rays

T5: 24 months, visit orthopedic surgeon, questionnaires, X-rays and MRI.

Onderzoeksproduct en/of interventie

During the T0 measurement patients fill out the VAS and WOMAC questionnaires and both a X-ray and MRI are performed. After this visit participants can start with the intervention that will last for two months. On forehand, patients will go to the OIM for two or three fittings (approximately 30 minutes per visit), after which the orthosis will be ready for use.

During the two month intervention period, where participants wear the orthosis, they have to

fill out a log every day. In this log they have to document whether they wear the orthosis or not and if they experience problems with the orthosis and whether their symptoms change. They are also asked to document their pain killer use in the log.

After 2 months (end of intervention period), 6 months and 18 months patients will visit the hospital again for the VAS and WOMAC and X-ray. At 12 and 24 months in addition a MRI will be performed. During visits T0 (start of intervention), 3 months (additional control visit), T2 (6 months), T3 (12 months) and T7 (24 months) patients also visit the orthopaedic surgeon (part of usual care).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• age between 25 and 60 years

• primary unilateral osteoarthritis in the tibiofemoral joint

• severity of osteoarthritis: moderate to severe (KL2 or higher) but below the level required for joint replacement

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• osteoarthritis in both knees

• generalized osteoarthritis (genetic)

• mechanical axis deviations > 10°

• psychological problems that would hinder wearing the orthosis

• primary retro patellar osteoarthritis

• BMI ≥ 30

• Balance problems (ASA 3 or higher)

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	10
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	04-07-2017

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47115
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6372
NTR-old	NTR6556
CCMO	NL58294.099.16
OMON	NL-OMON47115

Resultaten

Samenvatting resultaten
N/A