Feasibility study of an orthosis for treatment of Knee Osteoarthritis

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

Summary

ID

NL-OMON47115

Source
ToetsingOnline

Brief title
Orthosis in knee osteoarthritis

Condition

- Joint disorders

Synonym
degenerative joint disease, Osteoarthritis of the knee

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: D.H. Heijne stichting;OIM en Martini wetenschapsfonds,OIM

Intervention

Keyword: Distraction, Knee, Orthosis, Osteoarthritis

Outcome measures

Primary outcome

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.

Secondary outcome

- the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) (Bellamy et al. 1988) between all other time-points.

- Visual Analogue Scale (VAS) scores for pain (Bijur et al, 2001; Downie et al, 1978) between all time-points.

- assessment of articular cartilage volume with MRI (using the GENERIC protocol) between all time-points.

- severity of osteoarthritis determined with standardized knee X-rays between all time-points

- Visual Analogue Scale (VAS) score for satisfaction about the treatment result at two year follow-up

Study description

Background summary

Knee osteoarthritis (OA) is the most common joint disorder, and the lifetime risk of developing symptomatic knee OA has been estimated to be around 45%

(Murphy et al. 2008 Felson et al. 2000). If conservative treatment fails, total knee replacement (TKR) is a highly effective procedure that provides reliable relief from pain, improved physical function, and a high level of patient satisfaction (Hawker et al. 1998, Lutzner et al. 2009). The known limited lifespan of TKR, the high demand expectation of a prosthesis of relative young patient with knee osteoarthritis together with the increasing number of TKR*s constitutes costly healthcare (Blitton et al. 2009, Losina et al. 2009). Therefore, development of alternative treatments for knee OA, specifically those that can postpone a prosthesis, are needed.

A promising new treatment is the Knee Joint Distraction (KJD) treatment. Recent studies suggest that KJD treatment can reverse cartilage tissue structure damage in severe knee OA and at the same time results in significant clinical improvement (Intema et al. 2011). Joint distraction in its current form has some disadvantages, which limit its use. It is an invasive technique involving an external fixation frame, which patients have to wear for two months. This is a major psychological burden. It hinders patients during sleep and makes personal hygiene more difficult. The percutaneous pins of the frame often cause infection. Finally, after two months of distraction, the joints are very stiff, which also creates complications (pain and sometimes movement during anaesthesia).

We have developed an orthosis that takes the entire weight off the affected leg during walking without the use of percutaneous pins and joint distraction. The orthosis allows the knee to bend normally. We hypothesize, that this orthosis will also result in reduction of symptoms and regeneration of cartilage in an osteoarthritic knee joint.

Study objective

The primary objective of this study is to examine the effectiveness of the use of a load-reducing orthosis for two months on functioning (using a validated osteoarthritis function questionnaire (WOMAC)) in ten patients with osteoarthritis of the knee.

Study design

Observational pilot study.

Intervention

during two months patients use an non-weight bearing orthosis

Study burden and risks

The burden for patients involves wearing the orthosis and a sole on the other

foot, difficulties manoeuvring with the orthosis, pain experienced and other discomforts during the phase in which the orthosis is adjusted to the patient. Furthermore patients have to visit the hospital several times (questionnaires, X rays and MRI) in the follow-up period of 24 months. During a two month intervention period a log should be kept daily to monitor the use of the orthosis during daily activities. The major risk while using the orthosis is the change in balance experience which may result in falling and possibly in a bone fracture. The use of crutches may help, but can also be seen as an additional burden. The major benefit may be the improvement of OA symptoms and the curing of this disabilitating disorder in the long run.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• 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

Exclusion criteria

• symptomatic 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)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Orthosis
Registration:	No

Ethics review

Approved WMO Date:	27-06-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	22-10-2018
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-06-2024
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23870
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58294.099.16
OMON	NL-OMON23870

Study results

Date completed:	14-03-2022
Actual enrolment:	10