Effect of a soft brace on pain, knee stability and activity limitations in patients with knee osteoarthritis

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

Summary

ID

NL-OMON41788

Source
ToetsingOnline

Brief title
Amsterdam Osteoarthritis Brace (AOB) Study

Condition

- Joint disorders

Synonym
arthritis, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Brace, Knee, Knee Stability, Osteoarthritis

Outcome measures

Primary outcome

Knee pain, self-reported and performance-based knee joint stability and performance-based activity limitations (GUG, 10-m walk test).

Secondary outcome

Secondary study parameters are knee joint proprioception, skin sensitivity, pressure pain, postural balance, compliance, adherence, and side effects. Furthermore, socio-demographic variables (age, gender), comorbidity, body mass index (BMI), muscle strength, and self-reported activity limitations (WOMAC).

Study description

Background summary

Knee osteoarthritis (OA) is characterized by pain, knee instability and activity limitations. Knee bracing has been claimed as an option in the management of knee OA. Evidence has been found that a soft brace may reduce knee pain. The effect of a soft brace on knee pain has been attributed to the stimulation of cutaneous sensory fibres from skin mechanoreceptors, which might reduce knee instability. The effect of a soft brace on knee pain, knee instability and activity limitations has not been replicated and the underlying mechanisms are not clear.

Study objective

The primary aim of the study is (i) to assess the effect of a soft brace on pain, knee stability and activity limitations. Secondary aims are (ii) to assess the difference in effect of two knee soft braces (i.e., non-tight and tight) on pain and activity limitations, (iii) to explore underlying mechanisms of the therapeutic effect of a soft brace and (iv) to assess the late effects of two weeks application of a soft brace on pain, knee stability and activity

limitations in patients with knee osteoarthritis (OA).

Study design

A within-subject longitudinal design, comparing no soft brace versus soft brace, and comparing two types of soft braces: tight versus non-tight. The order of application of tight and non-tight soft braces will be randomized. After two weeks of wearing a soft brace late effects on pain, knee stability and activity limitations will be assessed and the satisfaction of wearing a soft brace will be reported.

Intervention

Soft knee braces will be used. Depending on the knee size, subjects will get a different size of the soft brace: with a variety between small and large. These different sizes will be used to differentiate between non-tight and tight soft braces. A non-tight brace will be one size looser than the tight brace.

Study burden and risks

The risk of wearing a soft-brace on side effects is negligible. Total risk of adverse events during the assessments and during walking on the treadmill is also negligible. The risk on adverse events is negligible during the two weeks of wearing the soft brace. When participants are satisfied in wearing the soft-brace, they may keep them and wear them for a longer time.

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

knee osteoarthritis based on the ACR criteria, age between the 50 and 80 years old, Body Mass Index (BMI) between 20 and 30 kg/m2, a maximal score of 7 on the numeric rate scale (NRS) for pain intensity during the past two weeks and having the perception of an episode of buckling, shifting or giving way of the knee in the past three months

Exclusion criteria

Total knee replacement, rheumatoid arthritis or any other form of inflammatory arthritis (i.e., crystal arthropathy or septic arthritis).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2015
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	soft brace
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL51872.029.15