Splinting for carpometacarpal osteoarthritis: which splint reduces pain the most?

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(1) To analyze differences in pain and function in patients with CMC-1 osteoarthritis after application of a custom made orthosis and an off-the-shelf orthosis (Push brace) (2) To measure compliance and factors influencing compliance with splint...

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

Summary

ID

NL-OMON38771

Source
ToetsingOnline

Brief title
Splinting for carpometacarpal osteoarthritis.

Condition

- Joint disorders

Synonym
degenerative joint disease of the basal joint of the thumb, Osteoarthritis of the CMC-1 joint

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Nea Company, fabrikant van de Push ortho Duimbrace CMC. Deze verstrekt kosteloos de benodigde Push-

braces voor het onderzoek, zonder invloed te hebben op het onderzoek of de resultaten. Er is geen financiele vergoeding.

Intervention

Keyword: Carpometacarpal osteoarthritis, Splint

Outcome measures

Primary outcome

Pain, measured on a 100 mm visual analogue scale (VAS).

Secondary outcome

Handfunction and compliance.

Study description

Background summary

Thumb carpometacarpal osteoarthritis (CMC-1) is a common disease, especially in the female population aged 40 and up. The main complaint is pain during use of the thumb and loss of function due to pain. There are many orthoses available to treat these symptoms, it is however not known which type reduces pain the most, which orthosis is preferred by patients and which factors influence compliance with splint therapy.

Study objective

(1) To analyze differences in pain and function in patients with CMC-1 osteoarthritis after application of a custom made orthosis and an off-the-shelf orthosis (Push brace)
(2) To measure compliance and factors influencing compliance with splint therapy for carpometacarpal osteoarthritis.

Study design

Prospective cross-over randomised controlled trial.

Intervention

Patients will first receive one orthosis, to be used for two weeks. After a 2 week washout period they will be given a second orthosis for another two weeks.

Measurements will take place before and after each test period. The order in which the orthoses will be provided will be randomised.

Study burden and risks

There will be four visits to our centres during this study instead of two to three visits that would occur in daily practice. During visits the orthosis will be custom made, the off-the-shelf brace will be fitted and tests will be performed. Besides, patients will be asked to fill out 4 questionnaires and to keep a diary daily. There will be no invasive tests or other treatments. Both orthoses are safe to use and will not harm patients.
At the beginning of the study a recent X-ray (<1 year old) has to be available of every patient for classification of the osteoarthritis. This corresponds to standard care for patients visiting the outpatient clinic. Therefore we do not see this as an extra incriminating research for the patients included in the study.

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

- Primary CMC-1 osteoarthritis, proven by X-ray, which explains patient complaints.
- Age >= 18 years.

Exclusion criteria

- Secondary CMC-1 osteoarthritis.
- Previous hand surgery for CMC-1 osteoarthritis.
- Corticosteroid injection in the last 6 months.
- Other hand specific diseases like rheumatoid arthritis, carpal tunnel syndrome, radiocarpal osteoarthritis that interfere with study results.
- Primary arthritis of the STT joint. In case of a combined arthritis of CMC-1 and STT patients will be included, unless arthritis of STT is more prominent.
- Insufficient command of the Dutch language.
- Serious cognitive disorders that will inhibit the patient in expressing the VAS scores and answering the questionnaires.

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):	15-10-2013
Enrollment:	80

Type:	Actual

Medical products/devices used

Generic name:	Push ortho Thumb Brace CMC
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL42987.042.13