Splinting for carpometacarpal osteoarthritis.

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There are many orthoses available to treat the symptoms caused by thumb carpometacarpal osteoarthritis. It is however not known which type reduces pain the most, which orthosis is preferred by patients and which factors influence compliance with...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27837

Bron
NTR

Verkorte titel
Splinting for carpometacarpal osteoarthritis.

Aandoening

Thumb carpometacarpal osteoarthritis (CMC-1) / CMC-1 artrose

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.

Ondersteuning

Primaire sponsor: Department of Rehabilitation Medicine,
University Medical Center Groningen.
Overige ondersteuning: Department of Rehabilitation Medicine,
University Medical Center Groningen.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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.

Objectives:

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.

Study population:

Patients with osteoarthritis of the CMC 1-joint.

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.

Main study parameters/endpoints:

1. Primary parameter: pain, measured on a 100 mm visual analogue scale (VAS);

2. Secondary parameters: handfunction, compliance.

Doel van het onderzoek

There are many orthoses available to treat the symptoms caused by thumb carpometacarpal osteoarthritis. 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.

We will perform a prospective cross-over randomised controlled trial to:

1. 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. Measure compliance and factors influencing compliance with splint therapy for carpometacarpal osteoarthritis.

Onderzoeksopzet

T=0: Questionnaires, baseline tests: Jebsen, nine-hole-peg test, pinch grip and key grip;

T= week 1+2: Test orthosis 1: daily diary; end week 2: questionnaire, Jebsen, nine-hole-peg test, pinch grip and key grip;

T= week 3+4: Wash out periode: daily diary; end week 4: questionnaire, Jebsen, nine-hole-peg test, pinch grip and key grip;

T= week 5+6: Test orthosis 2: daily diary; end week 6: questionnaire, Jebsen, nine-hole-peg test, pinch grip and key grip, semi-structured interview.

Onderzoeksproduct en/of interventie

In this prospective cross-over randomised controlled trial patients will use 2 types of orthoses: the off-the-shelf orthosis (Push-brace) and a custom-made orthosis.

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. The order in which the orthoses will be provided will be randomised.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary CMC-1 osteoarthritis, not caused by trauma or other diseases, proven by X-ray which explains patient complaints;

2. Age ≥ 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Secondary CMC-1 osteoarthritis;

2. Previous hand surgery for CMC-1 osteoarthritis;

3. Corticosteroid injection in the last 6 months;

4. Other hand specific diseases like rheumatoid arthritis, carpal tunnel syndrome, radiocarpal osteoarthritis that interfere with study results;

5. Primary arthritis of the scaphoid-trapezium-trapezoideum (STT) joint. In case of a combined arthritis of CMC-1 and STT patients will be included, unless arthritis of STT is more prominent;

6. Insufficient command of the Dutch language;

7. Serious cognitive disorders that will inhibit the patient in expressing the VAS scores and answering the questionnaires.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2013
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-05-2013
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	NL3812
NTR-old	NTR3978
Ander register	METC UMC Groningen : 2013.55
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A