Manometric TMC brace: a randomised crossover trial

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

Samenvatting

ID

NL-OMON20275

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Osteoarthritis, duimartrose

Ondersteuning

Primaire sponsor: Department of orthopedics, Reinier de Graaf hospital
Overige ondersteuning: Department of orthopedics, Reinier de Graaf hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient satisfaction, the primary outcome, is measured using the validated Dutch version of the Quebec User Evaluation of Satisfaction with Assistive Technology (D-QUEST). Since no

literature is published yet about the minimally clinically important difference for the D-QUEST, we defined a value for ourselves. A difference in score on the D-QUEST of more than 10%, this means 0.5 point difference on the 5-point outcome score, is considered to be the margin of clinical significance in this study.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Osteoarthritis (OA) is a degenerative joint disease. The trapeziometacarpal (TMC) joint is the carpometacarpal joint of the thumb. OA in the TMC joint is a common disease with a prevalence of 30% to 40% for postmenopausal women. One of the conservative treatments for TMC OA is a TMC brace. Evidence showed that TMC braces can reduce pain in TMC OA. Plaster braces are the current conventional treatment of TMC OA in the Reinier de Graaf hospital. Recently, Manometric developed a 3D printed custom-made brace, based on a 3D scan of the patient's' hand. It is made out of light materials and options for personalisation are provided.

Objective: the aim of this randomised crossover trial is to compare the Manometric TMC brace with conventional plaster braces in terms of patient satisfaction, pain, hand function, compliance and patient preference.

Study design: randomised crossover trial with two 4-week study periods and 1-week washout period in between.

Study population: 52 patients of the Reinier de Graaf Hospital (RdGG) with TMC OA indicated for brace therapy and who meet all inclusion and none of the exclusion criteria.

Intervention: Patients will receive both the Manometric and plaster brace, since the study has a crossover design. Patients will be randomised for the order of their treatment.

Primary study outcomes: Patient satisfaction, the primary outcome, measured with the D-QUEST, is compared between the Manometric and plaster brace. Patient satisfaction, compliance and patient preference are thought to be superior for the Manometric brace, compared to the plaster brace. Pain and hand function are thought to obtain equal results between the two treatments.

Doel van het onderzoek

The hypothesis is that the Manometric brace is superior to conventional plaster braces in terms of patient satisfaction, compliance and patient preference. For pain and hand function, no superior outcomes are expected for the Manometric brace compared to the plaster braces.

Onderzoeksopzet

The study consists of two 4-week treatment periods with 1-week washout period in between. VAS, QuickDASH, pinch and grip score are assessed at baseline and at week 4, 5 and 9. The D-QUEST is assessed at the 4th and 9th week. Patient preference is asked at the end of the two treatment periods. Compliance is reported by a daily log during the two 4-week treatment periods.

Onderzoeksproduct en/of interventie

Patients will receive both the Manometric and the plaster brace for four weeks. Between the two treatment periods is a one-week washout period.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical and radiological diagnosis of osteoarthritis (OA) in the TMC joint.

- OA grade 1, 2 of 3 (according to the Kellgren-Lawrence classification system).

- Age ≥18

- Signed informed consent

- Sufficiently able to understand Dutch

In case of bilateral TMC OA, patients who only need a brace for one hand are included, or if they are willing to wait till after the study for a brace for their second hand. The most symptomatic side is included in the study, based on clinical and radiological assessment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Disease in the affected hand or wrist other than TMC OA that may interfere with treatment or bias
the outcome (OA in radiocarpal joints, underlying inflammatory rheumatic disease, neurovascular disorder affecting
the upper limb, fracture in the past 6 months, significant hand injuries)

- Other (current) therapy for TMC OA (corticosteroid injection in the past 6 months, surgery in the affected TMC joint)

- Insufficient knowledge of the Dutch language

- Mental illness

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	52
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	10-10-2018
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	NL7326
NTR-old	NTR7542
Ander register	METC ZWH : METC 18-109

Resultaten

Samenvatting resultaten
N/A