Manometric TMC brace: a randomised crossover trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20275

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Osteoarthritis, duimartrose

Sponsors and support

Primary sponsor: Department of orthopedics, Reinier de Graaf hospital
Source(s) of monetary or material Support: Department of orthopedics, Reinier de Graaf hospital

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes includes pain, measured by a 10-cm visual analogue scale (VAS), and hand function, measured in terms of grip and pinch strength. In addition, hand function and symptoms are assessed using the Dutch version of the QuickDASH. Compliance is quantified by the wearing time per day in hours, reported using a self-reported diary of each patient. At the end of the two treatment periods, patient preference for one of the two braces is asked.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

Public
Reinier de Graaf Groep
G. Kraan
Delft 2525 AD
The Netherlands
+31 (0)15 260 3197
Scientific
Reinier de Graaf Groep
G. Kraan
Delft 2525 AD
The Netherlands
+31 (0)15 260 3197

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2019
Enrollment:	52
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	10-10-2018
Application type:	First submission

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
NTR-new	NL7326
NTR-old	NTR7542
Other	METC ZWH : METC 18-109

Study results

Summary results

N/A