

Comparison between the Manometric brace and conventional plaster braces for patients with osteoarthritis of the trapeziometacarpal joint: a randomised crossover trial

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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.

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

Summary

ID

NL-OMON48108

Source

ToetsingOnline

Brief title

Manometric TMC brace: a randomised crossover trial

Condition

- Joint disorders

Synonym

Osteoarthritis; degenerative joint disease

Research involving

Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Afdeling orthopedie; Reinier de Graaf Gasthuis

Intervention

Keyword: Orthoses, Osteoarthritis, Trapeziometacarpal joint

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, was 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

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.

(for references, refer to the research protocol introduction, page 10 and references, page 39))

Study 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 treatment periods and 1-week wash-out period in between.

Intervention

Patients will wear both the Manometric brace and the plaster brace for four weeks. A washout period of 1 week is between the treatment periods.

Study burden and risks

After risk analysis, it can be concluded that there are minimal risks for participating patients. Participating in this study requires extra appointments in the hospital.

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

- Clinical and radiological diagnosis osteoarthritis (OA) in the TMC joint
- OA grade 1, 2 or 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 study 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)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2019
Enrollment:	52
Type:	Actual

Medical products/devices used

Generic name:	Manometric TMC brace
Registration:	No

Ethics review

Approved WMO	
Date:	19-02-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	12-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 02-07-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	NL67750.098.18