The effect of exercise therapy in patients with thumb base osteoarthritis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21555

Source
NTR

Health condition

Thumb base osteoarthritis, CMC-1 OA, duimbasis artrose, basal joint arthritis

Sponsors and support

Primary sponsor: - Erasmus Medical Center Rotterdam
- Handtherapie Nederland B.V.
- Xpert Clinic Nederland
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

- Pain intensity

- Limitations in activities of daily life

- Pinch & grip strength

Secondary outcome

- Return to work

- Patient satisfaction

- Secondary treatment

Study description

Background summary

SUMMARY
Background: Osteoarthritis (OA) of the thumb base joint (CMC-1) is a common disorder. More insight in the effect of conservative interventions is needed due to a lack of studies of high methodological quality.

Research Questions: Primary research question (I): what is the effect of a combination of exercise therapy and splinting compared to splinting alone on pain intensity, limitations in activities of daily life (ADL) and pinch & grip strength in patients with CMC-1 OA? Secondary research questions: (II) What is the effect of a combination of exercise therapy and splinting compared to splinting alone on return to work and patient satisfaction in patients with CMC-1 OA? (III) Which baseline determinants can predict outcome on pain intensity, limitations in ADL and pinch & grip strength in patients with CMC-1 OA?

Design: Prospective open cohort with propensity score matching (PSM). Exercise therapy combined with splinting will be compared with splinting alone. Data collection will be part of usual care.

Population: All patients with CMC-1 OA referred by hand surgeons of Xpert Clinic for hand therapy, in a total of ten clinics in the Netherlands.

Parameters and data collection: Primary outcomes include pain intensity (visual analogue scale), limitations in activities of daily life (Michigan Hand Outcomes Questionnaire) and pinch & grip strength (Biometrics E-link ©). Secondary outcomes include return to work and patient satisfaction.

Analyses: After PSM, linear mixed models regression analyses will be conducted with respect to the primary research question (I) and secondary research question (II). Furthermore,

independent samples t-tests and the Mann-Whitney test will be used for the secondary research question (I). Multiple imputation will be used in the case of missing data.

Key words: Thumb, carpometacarpal joint, osteoarthritis, exercise therapy, propensity score

Study objective

The hypothesis is that a combination of exercise therapy and splinting is superior to splinting alone in the treatment of patients with thumb base osteoarthritis.

Study design

Baseline

6 weeks

3 months

12 months

Intervention

Exercise therapy and splinting is compared with splinting alone

Contacts

Public
Robbert Wouters
Leidsekade 82-D

Utrecht 3531 HA
The Netherlands
06-53531875
Scientific
Robbert Wouters
Leidsekade 82-D

Utrecht 3531 HA
The Netherlands
06-53531875

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Male/female and diagnosed with CMC-1 OA by the hand surgeon. The hand surgeon follows the guideline of the Dutch Society for Hand Surgery in the diagnostic process.15

- Eaton-Glickel20 stage I-IV

- Age ≥18

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Secondary basal joint arthritis (i.e. due to Bennet fracture)

- Comorbidities that may interfere with treatment/ bias outcome (i.e. rheumatoid arthritis, carpal tunnel syndrome, Quervain tenosynovitis)

- Patient history includes surgery that may interfere with treatment/ bias outcome

- Steroid injection <6 weeks in hand or wrist

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2015
Enrollment:	148
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-12-2015
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	NL5362
NTR-old	NTR5627
Other	: MEC-2015-691

Study results