CMC 1 total joint arthroplasty: rehabilitation or education? A controlled trial.

No registrations found.

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

Summary

ID

NL-OMON27423

Source
NTR

Brief title
TBA

Health condition

Osteoarthritis of the first carpometacarpal (CMC1) joint

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Daily hand function in patients with a total CMC1 joint arthroplasty after 3 months postoperatively, measured with the total score of the Michigan Hand Outcomes Questionnaire (MHOQ).

Secondary outcome

Pain, thumb range of motion, grip- and pinchstrength, complications, additional therapist- or surgeon visits, time to return to work and patient satisfaction.

Study description

Background summary

Joint wear of the thumb base or osteoarthritis of the first carpometacarpal (CMC1) joint is a common cause of pain and loss of function of the hand, especially in postmenopausal women. This can lead to severe reduction in quality of life due to limitations in activities of daily life. The prevalence of radiological arthrosis of the thumb base in people above 55 years of age is around 35%. The amount of scientific literature dealing with the application of a CMC1 total joint arthroplasty is very limited, moreover the post-operative approach hardly has been described. There are insufficient comparative studies of the additional value and effectiveness of postoperative hand therapy in thumb base osteoarthritis in general and, more specific, of CMC1 total joint arthroplasty. Aim of this study is to investigate whether postoperative rehabilitation with hand therapy after CMC1 total joint arthroplasty leads to better results than education only in the short term.

Study objective

Supervised rehabilitation with hand therapy in the first three months after total joint arthroplasty is beneficial to education only, in improving functional outcome.

Study design

Preoperatively, 3 months and 1 year postoperatively

Intervention

A historic cohort (resulting from a completed randomized clinical trial) with standard care (supervised rehabilitation with hand therapy) will be compared with a prospective cohort of people who only received oral and written education about the surgery, the postoperative period and expected recovery process.

Contacts

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Eligibility criteria

Inclusion criteria

Women aged 40 years or older with CMC1 osteoarthritis Eaton Glickel stage II or III (clinical and X-ray findings) who will receive a total CMC1 joint arthroplasty (Maïa® prosthesis, Groupe Lépine, Genay, France) .

Exclusion criteria

- Surgery for trapeziometacarpal osteoarthritis on the same hand in the past.
- Total joint arthroplasty on the contralateral hand in the past.
- Secondary trapeziometacarpal osteoarthritis as result of trauma, rheumatoid arthritis, systemic lupus or gout.
- Symptomatic carpal tunnel syndrome in same hand.
- Symptomatic Quervain's tenosynovitis in same hand.
- Neurological or other disorders of the affected side that can influence postoperative rehabilitation.
- Insufficient knowledge of Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-09-2018
Enrollment:	62
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-04-2019
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	NL7654
Other	METC Isala, Zwolle : METC180713

Study results