

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

Gepubliceerd: 10-04-2019 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27423

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

Osteoarthritis of the first carpometacarpal (CMC1) joint

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Preoperatively, 3 months and 1 year postoperatively

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Isala

EDJ Bonhof-Jansen

038-4247182

Wetenschappelijk

Isala

EDJ Bonhof-Jansen

038-4247182

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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) .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	03-09-2018
Aantal proefpersonen:	62
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	10-04-2019
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	NL7654

Register

Ander register

ID

METC Isala, Zwolle : METC180713

Resultaten