Distractie van het duimbasisgewricht: 6 versus 8 weken.

Gepubliceerd: 15-09-2019 Laatst bijgewerkt: 15-05-2024

This study will test the primary hypothesis that there is a difference in PROMIS Physical Function Upper Extremity Short Form (PROMIS UE SF) score at 1 year after 6 or 8 weeks of first carpometacarpal joint distraction.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27832

Bron
NTR

Verkorte titel
CMC1 joint distraction

Aandoening

Carpometacarpal osteoarthritis of the first joint (CMC1 OA)
Trapeziometacarpal osteoarthritis (TMC OA)

Ondersteuning

Primaire sponsor: This study was partially funded by the St. Antonius Hospital trough an innovation grant.
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in PROMIS Physical Function Upper Extremity Short Form (PROMIS UE SF) score at 1 year after 6 or 8 weeks of first carpometacarpal joint distraction.

Toelichting onderzoek

Achtergrond van het onderzoek

Joint distraction for first carpometacarpal (CMC1) OA is a technical feasible and innovative therapy for relatively young patients with severe symptoms. Spaans et al. conclude that joint distraction can provide clinical benefits in patients with CMC1 joint OA. It could result in postponing invasive surgical interventions for CMC1 OA. In this recent prospective pilot study five patients were treated and show favorable results - reduction of pain and improvement of function at one year. Nowadays 40 patients are treated with CMC1 joint distraction. On average, patients report less pain and better physical function compared to pre-operative scores. Two years post-operatively, the average clinical parameters further improved over time.
Among patients suffering from ankle and knee OA, joint distraction is an accepted treatment with excellent results, clinical improvement, and repair of joint cartilage. Van der Woude et al. shows that five years post-treatment, patients still report clinical improvement. In this study, all patients (n = 20) had the external distractor device in place for a duration of 8 weeks. A more recent study performed by the same research team shows that six weeks of distraction therapy has similar 1-year results compared to eight weeks of joint distraction. In comparison, patients in the six-week group had significantly less pin tract infections during the distraction period than patients in the eight-week group (55% versus 85% respectively; p = 0.038). It is also thought that the distracted joint will be less stiff when immobilized for a shorter period of time. In daily clinical practise the treatment of knee distraction has been reduced to a period of 6 weeks nowadays. It is unknown if six weeks of distraction is also sufficient for clinical improvements among patients with symptoms of CMC1 OA.
Therefore, this study will test the primary hypothesis that there is a difference in PROMIS Physical Function Upper Extremity Short Form (PROMIS UE SF) score at 1 year after 6 or 8 weeks of first carpometacarpal joint distraction.

Doel van het onderzoek

This study will test the primary hypothesis that there is a difference in PROMIS Physical Function Upper Extremity Short Form (PROMIS UE SF) score at 1 year after 6 or 8 weeks of first carpometacarpal joint distraction.

Onderzoeksopzet

3/4 weeks (Group A/B), 6/8weeks (Group A/B), 3 months, 6 months, 12 months, 2 years and 5 years post-distraction

Onderzoeksproduct en/of interventie

A standard hand distraction device will be placed over the affected CMC1 joint. The external fixator will be anchored transcutaneous with 2 proximal pins in the trapezium and two distal pins in the first metacarpal. The device will bridge the CMC1 joint. Intra-operatively the joint will be distracted 3.0 mm. This will be checked on X-ray. The distractor is left in situ for a total period of 6 (Group A) weeks or 8 (Group B) weeks. To protect the distractor and to prevent inconveniences to the patient due to the distractor, a custom-made brace will be fitted to cover the distractor. Hygiene instructions regarding pin entry point maintenance will be given and evaluated during postoperative visits. For patients in group A the device will be removed 6 after placing, for patients in group B the device will be removed 8 weeks after placing, both in the outpatient clinic and followed by standard care physical therapy.

Contactpersonen

Publiek

St. Antonius Hospital
Janna Ottenhoff

N/a

Wetenschappelijk

St. Antonius Hospital
Janna Ottenhoff

N/a

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age < 65 years
- Patients considered for operative intervention for CMC1 OA according to standard clinical practice
- Radiological joint damage: Eaton Littler classification II or III
- Failed non-operative treatment (e.g. splint for at least 3 months)
- Established indication for invasive surgical treatment

- Willingness to participate in the study and ability to understand distractor maintenance and hygiene instructions
- Location: St. Antonius Ziekenhuis in Nieuwegein or Utrecht

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unable to attend follow-up appointments
- Inflammatory or rheumatoid arthritis present or in history
- >30% joint subluxation
- Involvement of STT joint
- Surgical treatment of the CMC joint in the past
- Use of immunosuppressive or chemotherapeutic drugs
- Hypermobility syndrome
- Having syndromatic diseases

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-12-2019
Aantal proefpersonen:	68
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A/

Ethische beoordeling

Positief advies

Datum:	15-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48014
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8016
CCMO	NL68225.100.18
OMON	NL-OMON48014

Resultaten

Samenvatting resultaten
N/A