Joint distraction for thumb base osteoarthritis

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

Summary

ID

NL-OMON44915

Source
ToetsingOnline

Brief title
Joint distraction for thumb base osteoarthritis

Condition

- Joint disorders

Synonym
degenerative joint disease, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: subsidieaanvragen bij Annafonds en reumafonds

Intervention

Keyword: CMC 1 osteoarthritis, joint distraction, thumb base osteoarthritis, treatment

Outcome measures

Primary outcome

The main study parameter is the clinical outcome, determined by VAS for pain, Range of Motion, strength, MHQ and DASH score at 2, 3, 6 and 12 months. Also, we would like to answer the question if invasive surgery can be postponed or prevented by CMC1-JD in patients requiring surgical treatment of an osteoarthritic CMC1 joint after 12 months of follow-up.

Secondary outcome

Secondary parameters are the joint space on X-ray examination and the aspects (including thickness) of the cartilage on MRI.

Study description

Background summary

Carpometacarpal 1 (CMC1) osteoarthritis affects 36% of people over 55 years and is more prevalent in woman. Established OA of the CMC1 joint severely affects hand function due to pain, weakness, and deformity, all resulting in marked disability. Most patients are forced to make adjustments to work and leisure activities.
In early phases in the progression of CMC1 osteoarthritis, conservative treatment methods can bring relief to some patients. However, for some other patients symptom relief with these non-operative managements is inadequate or only temporary. The majority of progressive cases eventually requires some form of operative intervention to regain functionality. In the past decades, a multitude of surgical interventions have been proposed and used. However, no single operative technique has gained fully satisfactory results.
In recent years, joint distraction has been proven a very adequate, minimally invasive method to treat osteoarthritis in knees and ankles. This novel and very promising approach to osteoarthritis has not yet been applied to the

common problem of thumb base osteoarthritis.

Study objective

To evaluate the effect of CMC1 joint distraction in patients with failed conservative treatment of Eaton Littler grade II or III CMC osteoarthritis. The hypothesis is that results will mirror those in knee and ankle joint distraction, yielding reduced pain and improved functionality based on (partial) cartilage regeneration, as measured by the MHQ and DASH questionnaire, VAS score, strength and range of motion. In these cases, invasive surgery (trapezectomy/ prosthesis/arthrodesis) may be delayed or prevented.

Study design

A pilot study (pilot I) of 5 patients will precede a non-randomised, non-blinded, prospective study (pilot II) with 15 patients with a 1-year follow up period.

Intervention

A standard hand distraction device will be placed over the affected CMC1 joint under regional or general anesthesia. The external fixator will be anchored transcutaneously with 2 proximal pins in the trapezium and two distal pins in the first metacarpal, thus bridging the CMC1 joint. Intra-operatively the joint will be distracted 1.0 mm. Postoperatively, patients will distract the joint themselves by 0.5 mm/day, until a total distraction of 3.0 mm is reached four days later. This will be checked on X-ray. The distractor is left in situ for a total period of 8 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. After 8 weeks the frame is removed in the outpatient clinic, followed by standard care physical therapy.

Study burden and risks

Clinic visits
Patients will be requested to visit the outpatient clinic preoperatively, every 2 weeks during the distraction therapy and at 3, 6 and 12 months postoperatively. These clinic visits are in accordance to the standard hand surgery follow up visits and are not altered for study participation. At clinic visits, patients are asked to fill out questionnaires (VAS, MHQ and DASH). At these visits, patients will also be seen by a hand therapist for measurements of strength and range of motion.
Surgical treatment and postoperative care

Added burden associated with study participation is the 8 weeks of distractor presence instead of 4 weeks of plaster of Paris which is the norm for invasive surgery. A potential risk is that of disappointing results of the distractor treatment. In these cases, the initially indicated invasive surgical procedure can still be performed, albeit with delay caused by study participation.
Standard X-ray imaging will be done at clinic visits pre-operatively, perioperatively, during distraction therapy (every 2 weeks), after distractor removal at 8 weeks, and at 3, 6 and 12 months postoperatively.
Complications associated with distractor treatment
Participation risks are associated with the placement and presence of the distractor device. All potential complications are expected to occur in the same prevalence as those known for established therapies such as metacarpal bone distraction or external fixation of comminuted fractures of the hand. These potential complications include:
1. pin tract infections. Incidence of pin tract infections in hand fractures is 6% according to the literature. Patients will be educated daily distractor hygiene routines. At clinic visits the presence of infections is evaluated. In the very unlikely case of a severely neglected pin tract infection, progression into osteomyelitis of the trapezium or first metacarpal could occur. Early and established pin tract infections can be adequately treated with oral and local antibiotics.
2. Loosening or dislodging of the device due to direct external forces. To prevent snagging or bumping of the distractor device, a customized thermoplastic splint is fashioned directly after placement of the device to provide cover and protection. If for any reason the device is loosened or dislodged, re-fixation or removal will follow varying per case.
3. disappointing result. In case distraction therapy yields insufficient results, the established options of invasive surgery will still be possible. Study participation is not expected to influence results of the chosen invasive surgery procedure, albeit the timing procedure will have been postponed for study participation.

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

Patients considered for operative intervention for CMC1 OA according to standard clinical practice
Age below 65 years
Radiological joint damage: Eaton Littler classification II or III
Failed conservative treatment
Established indication for invasive surgical treatment
Willingness to participate in the study and ability to understand distractor maintenance and hygiene instructions

Exclusion criteria

Psychological inabilities or difficult to instruct
Not able to undergo MRI examination (standard protocol)
Inflammatory or rheumatoid arthritis present or in history
> 30% joint subluxation
Involvement of scaphoid-trapezium-trapezoid (STT) joint
Surgical treatment of the CMC joint in the past

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-10-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL44490.100.13