Arthrocentesis as initial treatment of arthropathy of the temporomandibular joint.

Gepubliceerd: 23-10-2008 Laatst bijgewerkt: 18-08-2022

Arthrocentesis of the temporomandibular joint as initial treatment of arthropathy is more cost-effective than usual care.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25474

Bron
NTR

Verkorte titel
STArt

Aandoening

Arthropathy of the Temporomandibular Joint

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main outcome measure is reduction of pain in the TMJ (0 – 100 mm VAS).
Furthermore, a cost-utility analysis will be performed with the QALY (Quality Adjusted Life Years) as primary outcome measure. The VAS pain scale (0-100) will be used as primary outcome measure of the cost-effectiveness analysis. QALYs used in the additionally planned cost-utility analysis will be derived from EQ-5D [EuroQoL group, 1990] (10) results assessed in the context of the current study.

Toelichting onderzoek

Achtergrond van het onderzoek

Most articular disorders of the TMJ are degenerative processes, primarily affecting the articular tissues and eventually leading to destruction of bone and surrounding structures. Common clinical symptoms are pain, a resticted mouth opening, joint sounds and problems with chewing food. The disease is usually treated conservatively with analgesic drugs (NSAIDs), oral appliances and physical therapy. Conservative treatment for degenerative joint disorders is often timeconsuming, and has unpredictable successrates. Conservative treatment does not stop the degenerative process directly and will have its influence with time. Chronic cases irresponsive to conservative care are indications for surgical intervention (viz. arthrocentesis (lavage) and artroscopy). Arthrocentesis is a simplified arthroscopy surgery without the use of a camera and intra-articular instruments and is rapid, minimally invasive and safe. Earlier indication of arthrocentesis may cease further degeneration of the articular tissues and as a matter of fact, it could be cost effective. - Objective: The aim is to study the effectiveness of arthrocentesis as initial treatment of arthropathy as compared to usual care. - Study design: Randomized Controlled Trial - Study population: Patients with TMJ arthropathy - Intervention: Patients are randomly assigned to one of two treatment arms. Patients undergo an arthrocentesis procedure (arm 1) or "care as usual" (arm 2). - Outcome measures: Main outcome measure is pain in the TMJ (0 – 100 mm VAS). Secondary outcome measures are mandibular function, Quality of Life, and bony changes in the TMJ. - Sample size calculation/data analysis: Statistical analysis uses ‘Generalized Estimating Equations’ (GEE) models (sample-size: 92 participants needed for a power of 0.80). - Economic evaluation: An economic evaluation to assess the cost-effectiveness is part of the clinical study (incremental costs per additional point on the VAS). Also, a cost-utility analysis (in QALY) will be performed. The economic evaluation will be conducted from a societal perspective, comparing the balance between costs and health outcomes between patients in both arms. - Time schedule: The time needed to create the final study protocol and approval of the METC is approx. 3 months; for inclusion of patients, 6 months; for the study and follow-up, 9 months and for publication, 6 months. Total study length is 2 years.

Doel van het onderzoek

Arthrocentesis of the temporomandibular joint as initial treatment of arthropathy is more cost-effective than usual care.

Onderzoeksopzet

Follow-up is at baseline, 3, 12 and 26 weeks (X-rays at baseline and 26 weeks, psychosocial factors only at baseline).

Onderzoeksproduct en/of interventie

Patients assigned to arm 1 undergo an arthrocentesis procedure. The procedure is done

under local anesthesia of the TMJ and takes place in a closed room under controlled conditions (prepared dental operation room). After the TMJ is localised by palpation, the points for insertion of the needles are marked. While the mouth is slightly opened, two 18 gauge injection needles are inserted into the TMJ about 6-8 mm apart from each other (7). One needle is connected to a medical infusion system to allow isotonic saline to enter the upper joint compartment. The other needle is connected to a tube to allow the fluid to exit the joint. In about 15 minutes, approximately 300 ml isotonic saline is washed through the joint, removing degradation products, cytokines and other inflammatory components. At the end of the procedure, the needles are removed from the joint, and the skin overlying the TMJ is covered with a sterile band aid. Immediately after the procedure, the participant can go home. The procedure takes about 30 minutes. The arthrocentesis procedure can be regarded as a simplied alternative to the well-known arthroscopy procedure (also known as "endoscopic joint surgery"). In both procedures the joint is washed with isotonic saline. However, the most important difference between both procedures is that for the arthrocentesis procedure, no endoscopic camera and no surgical equipment is used in the joint. Removal of the unwanted matter in the joint in arthrocentesis is achieved purely by flow of the saline. Another important difference between both procedures is that the arthroscopy procedure is done under general anaesthesia, because of the size of the "portals". Arthrocentesis is in such a way a relatively noninvasive procedure compared to arthroscopy. Patients assigned to arm 2, will participate in the care as usual program. Participants are (A) prescribed a NSAID (600 mg) 3 dd, instructed to (B) use a soft diet (i.e. to avoid eating nuts, chewing gum, wine gums, hard sweets). Second (C), a custom made hard acrylic splint (oral appliance) is offered and patient are instructed to wear it during the night and 1 to 2 hours during the day to allow the patient to practice keeping the teeth apart. And lastly (D) patients undergo a physical therapy intervention program, aiming at minimizing teeth clenching and to practice smooth mandibular movements. The four modalities (A, B, C and D) are executed parallel and the lenght of the total care as usual program is 6 weeks.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age over 18 yrs

2. Pain in the TMJ

3. Complaints that persist after treatment with NSAID (Ibuprofen 3 x 600 mg dd, 2 wks)

4. Local anaesthesia of the TMJ yields alleviation of pain complaints

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Bony ankylosis of the TMJ

2. Reumatoid arthritis

3. History of TMJ surgery

4. Incompetence to speak the Dutch or English language

5. Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-01-2009
Aantal proefpersonen:	92
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1444
NTR-old	NTR1505
Ander register	: ZonMw 170991006
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A