Diagnostic arthroscopy versus arthrocentesis as initial treatment for arthralgia of the temporomandibular joint

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20171

Source
NTR

Brief title
DIAMOND

Health condition

Arthralgia, internal derangement and degenerative joint disease (i.e. osteoarthritis) of the temporomandibular joint

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Pain perceived by the patient during mandibular movement or function using the Visual Analogue Scale (VAS; ranging 0-100mm).

Secondary outcome

- Pain perceived by the patient at rest using the VAS (ranging 0-100mm)
- Maximum Interincisal Opening (MIO; in mm) without perceiving (increased) pain measured by the clinician with a caliper
- Maximum Interincisal Opening (MIO; in mm) measured by the clinician with a caliper
- Mandibular range of motion (MROM) measured by the clinician with a dental pocket probe (proal and lateral movements; in mm)
- Joint blocks and noises (i.e. clicks, crepitation, pops) perceived by the patient in the last 3 months (absent/ present)
- Impairment of mandibular function as perceived by the patient using the validated mandibular function impairment questionnaire (MFIQ; 17 items scored on a Likert scale, with the total score ranging 0-68)
- Cost-effectiveness (using the composite of the primary study outcome variable 'VAS-score during movement or function' and 'costs', and a second cost-effectiveness analysis using 'MFIQ-score' and 'costs')
- Safety (measured as kind and amount of adverse and serious adverse events)

Study description

Background summary

Internal derangement (ID) and degenerative joint disease (DJD) of the temporomandibular joint (TMJ) are the most common causes of arthralgia of the TMJ. When these disorders are symptomatic, elevated pro-inflammatory cytokines and degradation products are often present in the synovial fluid of the joint. The lavage of the joint with arthrocentesis as initial treatment may wash these harmful products away and is shown to be an (cost-)efficient way in reducing clinical symptoms of DJD and ID.

The more advanced procedure diagnostic arthroscopy/ single portal arthroscopic lysis and lavage under localized anesthesia also enables the lavage of the joint, but additionally allows lysis and localized injections with corticosteroids. Currently, diagnostic arthroscopy is only performed when arthrocentesis is proven to be insufficient in reducing clinical symptoms. Indicating diagnostic arthroscopy as first-line (therefore replacing arthrocentesis) treatment for TMJ-arthralgia may prevent further degeneration of the joint and reduce clinical symptoms more efficiently than arthrocentesis.

The aim of the study is therefore to evaluate the (cost-)efficiency of diagnostic arthroscopy in reducing clinical symptoms compared to arthrocentesis under local anesthesia as initial treatment in patients with arthralgia (with or without reduced mobility) of the TMJ.

The study design is a single-center single-blind randomized controlled trial, conducted in the University Medical Center Groningen (UMCG). An estimated 140 subjects will be randomized in two arms (50:50 ratio).

Study objective

Diagnostic arthroscopic (lysis and lavage) reduces clinical symptoms more rapidly and efficaciously than arthrocentesis.

Study design

3 months, 6 months and 12 months.

Intervention

Investigational intervention is diagnostic arthroscopic (lysis and lavage);
Control intervention is arthrocentesis

Contacts

Public
University Medical Center Groningen (UMCG)
Yang Hang Tang

(050) 361 25 61
Scientific
University Medical Center Groningen (UMCG)
Yang Hang Tang

(050) 361 25 61

Eligibility criteria

Inclusion criteria

- Patients aged > 18 years

- Arthralgia of the TMJ, proven with a diagnostic intra-articular injection with Ultracain DS Forte (articaine 4% + 1:100.000 adrenalin; Aventis Pharma, Hoevelaken, The Netherlands).

- TMJ pain still present after two weeks of NSAIDs (i.e. diclofenac 3 times daily 50mg)

- Symptoms presenting unilaterally or bilaterally with a maximal Visual Analog Scale (VAS)-score < 30 mm during movement or function of the contralateral joint, after anesthetizing the to be treated joint (thus avoiding the contralateral joint to be the cause of a limited mouth opening).

Exclusion criteria

- Systemic rheumatic disease (such as rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, Sjögren syndromes, psoriatic arthritis)

- Connective tissue disease (such as Marfan syndrome, Ehlers-Danlos syndrome, Osteogenesis Imperfecta)

- Bony ankylosis of the TMJ

- Congenital or acquired dentofacial deformity

- History of jaw trauma that resulted in jaw or joint pain, bony changes or mandibular growth restriction

- Prior arthrocentesis, (diagnostic) arthroscopy or open-TMJ surgery

- Psychiatric disorder (as diagnosed by a physician)

- Unwillingness to receive one of the study treatments

- Pregnancy at time of treatment

- Concurrent use of steroids, sedatives, muscle relaxants or anti-inflammatory drugs other than the previously prescribed NSAIDs

- Incompetence to speak the Dutch or English language

- Medical comorbidities such as coagulation disorders, diabetes mellitus type I or II, kidney failure, heart failure, cardiac ischemia, hypertension and history of HIV.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-01-2022
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-09-2021
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	NL9701
Other	METC UMCG : METc 2021/275

Study results