DIAGNOSTIC ARTHROSCOPY VERSUS ARTHROCENTESIS AS INITIAL TREATMENT FOR ARTHRALGIA OF THE TEMPOROMANDIBULAR JOINT
A mono-center single-blind randomized controlled trial

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To evaluate the effectiveness 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 temporomandibular...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50917

Source
ToetsingOnline

Brief title
DIAMOND trial

Condition

- Bone and joint therapeutic procedures

Synonym
Degeneration of the jaw joint, disc displacement

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arthrocentesis, Arthroscopy, Artralgia, Temporomandibular Joint

Outcome measures

Primary outcome

- Pain during mandibular movement or function using the VAS

Secondary outcome

- Pain perceived by the patient at rest using the VAS

- Maximum Interincisal Opening (MIO; in mm) without perceiving (increased) pain measured by the clinician

- MIO (in mm) measured by the clinician

- Mandibular range of motion (MROM) measured by the clinician (proal and lateral movements; in mm)

- Joint blocks and noises (i.e. clicks, crepitation, pops) perceived by patient in last 3 months (absent/ present)

- Impairment of mandibular function as perceived by 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 (qualitatively and quantitatively measured adverse and serious adverse

events)

Study description

Background summary

Degenerative joint disease (DJD) and internal derangement (ID) of the temporomandibular joint (TMJ) are two closely interrelated, but different entities. In DJD, secondary inflammatory components account for most of the symptoms such as joint pain, restricted or deviated mouth opening and joint clicks and noises. Similarly, due to the close correlation between both disorders, symptoms in ID may originate from the same inflammatory process. However, the displacement of the articular disc in ID is not exclusive to a pathological condition and may occur without any clinical symptoms. Hence when symptoms do occur, in both DJD and ID, elevated pro-inflammatory cytokines and degradation products are present in the synovial fluid. The lavage of the joint with arthrocentesis as initial treatment has therefore shown to be an effective and 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 treatment for DJD and ID may prevent further degeneration of the joint and reduce clinical symptoms more efficiently than arthrocentesis.

Study objective

To evaluate the effectiveness 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 temporomandibular joint.

Study design

Single-center single-blind randomized controlled trial. The study consists of two arms: one group receives arthrocentesis and the other group diagnostic arthroscopy.

Intervention

The intervention group receives diagnostic arthroscopy under local anesthesia and the control group receives arthrocentesis under local anesthesia.

Study burden and risks

Virtually, no additional risks are associated with participation in the study. The investigational procedure is not associated with an increased risk of complications in comparison to the control procedure. Both procedures are furthermore regularly performed in the research healthcare institution (UMCG) and are part of standard care. The two weeks of NSAID prescription and the diagnostic intra-articular injection give no additional risks, since these two steps are also performed when a patient does not choose to participate in the study. The burden on patients is expressed as a single additional short questionnaire that needs to be filled in during follow-up moments. Patients require no additional visits to the hospital, as follow-up moments of the study are scheduled during standard of care follow-up moments in the outpatient clinic.

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 aged 18 years or older.

- Arthralgia of the Temporomandibular joint (TMJ), proven with a diagnostic intra-articular injection with Ultracain DS Forte.

- TMJ pain still present after two weeks of NSAIDs

- Symptoms presenting unilaterally or bilaterally with at least one TMJ with a Visual Analog Scale-score < 30 mm during movement or function, after anesthetizing the contralateral joint.

Exclusion criteria

- Systemic rheumatic disease
- Bony ankylosis of the Temporomandibular Joint (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, muscle relaxants or anti-inflammatory drugs other than the previously prescribed NSAIDs
- Incompetence to speak the Dutch or English language
- 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
Primary purpose:	Treatment

Recruitment

NL

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

Ethics review

Approved WMO

Date:	30-08-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL76425.042.21
Other	Wordt geregistreerd na goedkeuring