

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

Gepubliceerd: 01-09-2021 Laatste bijgewerkt: 13-12-2022

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

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20171

### Bron

NTR

### Verkorte titel

DIAMOND

### Aandoening

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

### Ondersteuning

**Primaire sponsor:** UMCG

**Overige ondersteuning:** None

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

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).

### Doel van het onderzoek

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

### Onderzoeksopzet

3 months, 6 months and 12 months.

## Onderzoeksproduct en/of interventie

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

## Contactpersonen

### Publiek

University Medical Center Groningen (UMCG)  
Yang Hang Tang

(050) 361 25 61

### Wetenschappelijk

University Medical Center Groningen (UMCG)  
Yang Hang Tang

(050) 361 25 61

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

## Onderzoeksopzet

### Opzet

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

## Deelname

Nederland  
Status: Werving gestart  
(Verwachte) startdatum: 27-01-2022  
Aantal proefpersonen: 140  
Type: Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies  
Datum: 01-09-2021  
Soort: Eerste indiening

## 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        | NL9701                    |
| Ander register | METC UMCG : METc 2021/275 |

## Resultaten