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# A minimum invasive technique for patients with jaw joint dysfunction

**Submission date**
09/04/2022

**Recruitment status**
No longer recruiting

**Registration date**
02/11/2022

**Overall study status**
Completed

**Last Edited**
09/11/2023

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
The temporomandibular joint (TMJ), which connects the jawbone to the skull, may be affected by several disorders, including disc displacements and degenerative diseases. About 76% of the population will feel at some point a sign or symptom related to temporomandibular joint disorder (TMD), this usually will happen in women between the age of 20 and 40 years. A TMD might occur together with a limitation in function, making the patient unable to chew, speak or open their mouth satisfactorily. This leads to a dramatic change in the inside of the TMJ due to the limitation of its lubrication and progressive destruction. The study aims to compare different interventions to improve the health of the TMJ, thus improving all the functions of the jaw like chewing, speaking, or opening the mouth, as well as improving the quality of life of the patients.

Who can participate?
Patients aged 18 to 70 years who attend the TMJ department from the Oral Health Center - SAMS/Centro Clinico Lisboa Portugal who have had a previous locked TMJ but who have not had any kind of TMJ surgery or allergy to hyaluronic acid

What does the study involve?
The study involves answering a clinical questionnaire followed by a clinical exam, an MRI and CT scan. Participants are randomly allocated to one of two groups: the first group will be treated with an arthrocentesis which consists of washing out the jaw joint with a saline solution five times and then injecting 1 ml of hyaluronic acid inside the jaw followed by a mandibular manipulation manoeuvre to extend the TMJ capsule and allow the jaw to lubricate. The second group will receive therapeutical and behavioral guidelines to be followed during the follow-up period. The patients are evaluated after 1 month with a questionnaire and a clinical examination and again after a year from the first intervention where besides the questionnaire and the clinical examination they will undergo an MRI and a CT scan.

What are the possible benefits and risks of participating?
The benefits of this study could include an improvement in mandibular functions like chewing, speaking, or opening the mouth, less pain and an improvement in quality of life. The risks include

a transitory loss of feeling in the temporomandibular region, light swelling in front of the ear, and transitory stuffiness in the ear, the other possible risks are all minor and all of them are transitory.

Where is the study run from?
Centro Clinico SAMS Lisboa (Portugal)

When is the study starting and how long is it expected to run for?
January 2018 to July 2021

Who is funding the study?
1. Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas (Portugal)
2. QualyLive (Portugal)

Who is the main contact?
André Mariz Coelho Santos de Almeida, aalmeida@egasmoniz.edu.pt

# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
SAMSDPIAV1.1

# Study information

### Scientific Title
Evaluation of viscosupplementation and arthrocentesis associated with mandibular manipulation in the treatment of degenerative temporomandibular joint disease - a randomized clinical trial

### Acronym
EVAMMTDTJDRCT

### Study objectives
Current study hypothesis as of 05/04/2023:
Using viscosupplementation and arthrocentesis associated with mandibular manipulation is efficient and safe for controlling the evolution of degenerative joint disease in patients with disc displacement without reduction.

Previous study hypothesis:
Using viscosupplementation associated with mandibular manipulation is efficient and safe for controlling the evolution of degenerative joint disease in patients with disc displacement without reduction.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 06/03/2018, Ethics Commission of Hospital dos SAMS PICS do SBSI (President of the Ethics Commission Prof. Doutor Costa Martins; Cidade de Gabela 1, 1849-017 Lisboa, Portugal; +351 (0)218422000; Costa.Martins@sams.sbsi.pt), ref: 1/2018

### Study design
Randomized clinical trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Degenerative joint disease

## Interventions
Current interventions as of 05/04/2023:
Patients are randomly assigned in a 1:1 ratio. A random allocation sequence is performed using a randomization program (http://www.randomizer.org).

AHS Group:
30 randomly allocated patients will be diagnosed, evaluated for quality of life perception and submitted to magnetic resonance imaging and computed tomography of the temporomandibular joint (TMJ) before the first intervention and after treatment. During the interventions they will undergo mandibular manoeuvre (MM) associated with infiltration and wash out of 4 ml of physiological saline solution repeated five times and 1 ml high molecular weight HÁ is injected in the upper compartment of the TMJ with infiltration of 1 ml of high molecular weight HS (Osteonil® Plus) in the upper joint compartment.

MET Group:
30 randomly allocated patients will be diagnosed, assessed for quality of life perception and submitted to MRI and CT scanning of the TMJ before the first intervention and after treatment. During the interventions they will receive educational therapy and behavioural guidelines.

Previous interventions:
Patients are randomly assigned in a 1:1:1 ratio. A random allocation sequence is performed using a randomization program (http://www.randomizer.org).

Control group 1:
30 randomly allocated patients will be diagnosed, evaluated for quality of life perception and submitted to magnetic resonance imaging and computed tomography of the temporomandibular joint (TMJ) before the first intervention and after treatment. During the interventions they will undergo mandibular manoeuvre (MM) associated with infiltration and wash out of 4 ml of physiological saline solution repeated five times and 1 ml high molecular weight HÁ is injected in the upper compartment of the TMJ with infiltration of 1 ml of high molecular weight HS (Osteonil® Plus) in the upper joint compartment.

Control group 2:
30 randomly allocated patients will be diagnosed, assessed for quality of life perception and submitted to MRI and CT scanning of the TMJ before the first intervention and after treatment. During the interventions they will receive educational therapy and behavioural guidelines.

Intervention group:
Patients will be submitted to the MM technique associated with the infiltration of 1 ml of high molecular weight HS (Osteonil® Plus) into the upper joint compartment of one side or both sides if the involvement is bilateral, by a single-blind assessor at M0 and M1. Evaluators 1 and 2 will perform, respectively, a clinical evaluation and an evaluation of the imaging exams in M0, M1 and M2. In the case of adverse reactions, they will be told to communicate with the evaluators.

There are two follow-ups at 1 month and 12 months after treatment.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
The efficacy and safety of mandibular manipulation associated with viscosupplementation of the temporomandibular jaw, measured using:
1. Overall TMJ pain assessment with the visual analogue score (VAS) at baseline, 1 month and 12 months after treatment
2. Safety assessed by recording side effects throughout the study

### Secondary outcome measures
1. Masticatory muscle pain measured using the visual analogue score (VAS) at baseline, 1 month and 12 months after treatment
2. Mandibular range of motion is measured in millimeters with a Therabite Ruler in maximum opening position without pain at baseline, 1 month and 12 months after treatment
3. TMJ degenerative joint images on CT scan evaluated by a trained and calibrated blinded researcher at baseline and 12 months after treatment
4. TMJ disc position on MRI evaluated by a trained and calibrated blinded researcher at baseline and 12 months after treatment
5. Oral health-related quality of life measured using the Oral Health Impacts Profile (OHIP-14) at baseline, 1 month and 12 months after treatment

### Overall study start date
03/01/2018

### Completion date
10/07/2021

## Eligibility

### Key inclusion criteria
1. Both sexes
2. 18 to 70 years of age
3. Previous history of TMJ blocking
4. Acute or chronic temporomandibular disorder (TMD) uni- or bi-lateral

### Participant type(s)
Patient

### Age group
Mixed

### Sex
Both

### Target number of participants
90

### Total final enrolment
81

### Key exclusion criteria
1. Exclusively muscular TMD
2. Clinical history of TMJ fracture, ankylosis or surgery
3. Patients undergoing other kind of treatment for articular TMD

### Date of first enrolment
10/03/2019

### Date of final enrolment
16/11/2019

## Locations

### Countries of recruitment
Portugal

### Study participating centre
**SAMS Centro Clinico**
R. Fialho de Almeida 21
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## Sponsor information

### Organisation
Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas

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**Sponsor type**
Hospital/treatment centre

**Website**
https://www.sams.pt/UnidadesSaude/Paginas/HospitalSAMS.aspx

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Qualylife

**Funder Name**
Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
10/09/2023

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from André Mariz Coelho Santos de Almeida (aalmeida@egasmoniz.edu.pt). The individual data were collected according to the European Data Protection Board Guidelines under the guidance of the Head of Data Protection Impact Assessment at Serviços de Assitência Médica Social SAMS

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 30/04/2023 | 09/11/2023 | Yes | No |