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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

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Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized clinical trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
Lisboa
Portugal
1070-128

Sponsor information

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

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

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