

Using hyaluronic acid injections to treat jaw pain in patients with temporomandibular issues: a clinical study

Submission date 21/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/10/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/10/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Temporomandibular disorders (TMDs) are issues with the jaw joint and surrounding muscles, causing pain and difficulty opening the mouth. One type of TMD, called disc displacement without reduction (DDwoR), occurs when the disc in the jaw joint is out of place and doesn't return to its normal position, leading to pain and limited mouth movement. This study aims to compare three treatments to find out which one is best at reducing pain and improving jaw function.

Who can participate?

Adults (both men and women) diagnosed with DDwoR who have not had success with other treatments can participate. Healthy volunteers cannot join this study.

What does the study involve?

The study compares four treatments:

- Injections of hyaluronic acid (HA) into the jaw joint
- A procedure called arthrocentesis (which washes out the joint)
- Arthrocentesis combined with HA injections
- Jaw exercises (used as the control group)

Participants will be randomly assigned to one of these groups. Their pain levels, jaw function, and quality of life will be measured at the start, after 1 month, and after 12 months.

What are the possible benefits and risks of participating?

Participants may experience reduced pain and improved jaw movement. Risks are minimal but may include temporary pain or swelling at the injection site after the procedures.

Where is the study run from?

The study is being conducted at Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas (Portugal)

When is the study starting and how long is it expected to run for?
March 2018 to April 2024.

Who is funding the study?
The study is funded by Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas and Qualylife Portugal.

who is the main contact?
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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
ID042024

Study information

Scientific Title
Evaluation of viscosupplementation with hyaluronic acid in the treatment of refractory arthralgia in patients with disc displacement without reduction of the temporomandibular joint (TMJ): a randomized clinical trial

Acronym
EVHARCT

Study objectives

To demonstrate that HA infiltration associated with mandibular manipulation is superior in terms of effectiveness to the combination of arthrocentesis with HA and mandibular manipulation, arthrocentesis alone and mandibular manipulation, and mandibular exercises in patients with disc displacement without reduction and refractory arthralgia in the TMJ.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/10/2024, Ethics Commission of Hospital dos SAMS PICS do SBSI (Cidade de Gabela 1, Lisboa, 1849-017, Portugal; +351 218422000; Comissao.Etica@sams.pt), ref: ID04/2024

Study design

Interventional randomized controlled trial with parallel group design not blinded

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

Evaluation of efficacy on the treatment of refractory articular pain in patients with disc displacement without reduction unilateral or bilateral

Interventions

Hyaluronic Acid (HA) Injection Group:

Participants in this group receive an injection of 1 ml of hyaluronic acid directly into the jaw joint (temporomandibular joint - TMJ). This treatment is believed to reduce friction in the joint, improve movement, and alleviate pain.

Arthrocentesis Group:

In this group, participants undergo arthrocentesis, which is a procedure that flushes the TMJ with saline solution to remove debris and reduce inflammation. This method aims to improve joint mobility and reduce pain.

Arthrocentesis with Hyaluronic Acid (HA) Group:

Participants in this group first undergo the arthrocentesis procedure (flushing the joint), followed by an injection of 1 ml of hyaluronic acid. The combination of both techniques is expected to provide enhanced pain relief and joint function compared to either method alone.

Jaw Exercises (Control Group):

Participants in this group are instructed on performing specific jaw exercises to improve their jaw movement and reduce pain. These exercises are done at home, with follow-up to ensure compliance. This group serves as a comparison to the minimally invasive treatments.

The patients in this study underwent two intervention sessions. The first intervention was administered after the initial consultation, and a second intervention was given 30 days later

during a follow-up visit. After these interventions, patients were monitored through follow-up assessments conducted at 1 month and 12 months after the initial treatment to evaluate the long-term effects of the interventions on pain, jaw function, and overall quality of life.

At the time of treatment administration, participants were consecutively allocated (1:1:1:1) into treatment groups using a randomization tool prior to the procedures. The randomization process was handled by a technician who was not involved in any other procedures in the study. Opaque envelopes were used to ensure allocation concealment, and these envelopes were opened by the clinician immediately before administering the treatment. The order of the envelopes was determined independently before the study began by an investigator who was not involved in the study.

Intervention Type

Supplement

Primary outcome(s)

1. Chronic pain Intensity value according to the Graded Chronic Pain Scale at baseline, 1 month and 12 months
2. Mandibular range of motion according to the DC/TMD measures of pain free opening and maximum unassisted opening at baseline, 1 month and 12 months
3. DC/TMD diagnosis change using the DC/TMD classification system at baseline, 1 month and 12 months

Key secondary outcome(s)

1. Quality of life using the OHIP14 questionnaire at baseline, 1 month and 12 months
2. Jaw Functional Limitation using the Jaw functional limitation scale and the disability points according to the Graded Chronic Pain Scale at baseline, 1 month and 12 months
3. Overall TMJ pain assessment with the visual analogue score (VAS) at baseline, 1 month and 12 months after treatment
4. Overall Muscle pain assessment with the visual analogue score (VAS) at baseline, 1 month and 12 months after treatment

Completion date

01/04/2024

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

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Total final enrolment

97

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
4. Fibromialgia
5. Pregnancy
6. Patients who are blind, illiterate, or have reduced cognitive abilities that may interfere with communication, understanding of the study, response to questionnaires, or execution of instructions.
7. Known psychiatric or physical comorbidities that may interfere with communication or execution of instructions

Date of first enrolment

03/06/2021

Date of final enrolment

04/01/2023

Locations

Countries of recruitment

Portugal

Study participating centre

Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas - SAMS centro clínico

R. Fialho de Almeida 21

Lisboa

Portugal

1070-128

Sponsor information

Organisation

Facultad odontologia Universidad de Granada

Organisation

Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas

Organisation

Egas

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Serviços Assistência Médico Social - Sindicato dos Bancários Sul e Ilhas

Funder Name

Qualylife Portugal

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study are not expected to be made available due to data protection policy from the hospital where the study was done

IPD sharing plan summary

Not expected to be made available