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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

Registration date
22/10/2024

Overall study status
Completed

Last Edited
22/10/2024

Condition category
Mental and Behavioural Disorders

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Dental clinic, Hospital

Study type(s)
Treatment, Efficacy

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

Health condition(s) or problem(s) studied
Evaluation of efficacy on the treatment of refratary 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 measure
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

Secondary outcome measures
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

Overall study start date
06/03/2018

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
104

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. Preganancy
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

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Sponsor type
University/education

Website
https://www.ugr.es/universidad/organizacion/entidades/departamento-estomatologia

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/Paginas/default.aspx

Organisation
Egas

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Sponsor type
University/education

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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

Publication and dissemination plan
Planned publicaton in a peer-reviewed journal

Intention to publish date
06/09/2025

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