ISRCTN63941479 https://doi.org/10.1186/ISRCTN63941479

How dextrose prolotherapy can help relieve persistent temporomandibular joint pain and improve jaw function

Submission date
20/01/2025

Recruitment status
No longer recruiting

Registration date
21/01/2025

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Musculoskeletal Diseases

[ ] 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
This study aims to see how effective injecting 5% dextrose directly into the joint is for treating symptoms of temporomandibular joint (TMJ) disc displacement without reduction, which causes limited mouth opening, in patients who haven't responded to medication and physical therapy.

Who can participate?
Females aged 18 - 35 years old with temporomandibular joint disc displacement without reduction with limited mouth opening

What does the study involve?
Participants will be randomly divided into two groups to be treated either with a 5% dextrose or saline. Pain intensity on opening and closing is measured before the injection and 2 weeks, 2 months, and 6 months after the treatment.

What are the possible benefits and risks of participating?
The anticipated benefits of this study include improving the TMJ function and enhancing the limited mouth opening. The potential risks include flare-ups.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2023 to April 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
1. Yazan Sayed Taleb, yazan44.sayed@damascusuniversity.edu.sy
2. Dr Yasser Alsayed Tolibah, yasser94.tolibah@damascusuniversity.edu.sy or Yasseralsayedtolibah@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DN-02092024-306

Study information

Scientific Title
Dextrose prolotherapy effect in improving the temporomandibular joint disc displacement symptoms without reduction refractory to conservative treatment

Study objectives
The researchers evaluated the effectiveness of the 5% dextrose injection compared with placebo to test the hypothesis that it is more effective in relieving symptoms of a closed lock jaw.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 02/08/2021, Damascus University (Almazzeh St, Damascus, 20872, Syria; +963 (0) 90404840; dl.srd@damascusuniversity.edu.sy), ref: 561

Study design
Randomized triple-blinded controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Temporomandibular joint disc displacement without reduction

Interventions
Patients with symptoms of unilateral DDwoR with limited mouth opening were randomly assigned into two equal groups using the randomization tool from https://www.randomizer.org/. The study group received injections of 5% dextrose (D5W), while the control group received injections of 0.9% normal saline (NS).

The patient was placed in a semisupine position, the preauricular area was disinfected with povidone 4%, and a line was drawn from the lateral canthus to the most posterior and central point on the tragus (the Holmlund–Hellsing line), on this line 10 mm anterior to tragus, point A was marked and 10 mm below this point was marked other B (Figure 1).
The solution to be injected was prepared away from the patients' eyes according to the randomization process, and we asked the patient to open his mouth as wide as possible, the tip of a 27-gauge needle with 35 mm length was inserted starting at point B to a depth of approximately 25 mm in an anteromedial direction along the posterior portion of the condylar neck to reach the retrodiscal area and then was injected 1ml of solution (5% dextrose or saline) slowly after aspiration.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain assessed using the Visual Analogue Scale (VAS) at four timepoints: before injection (T0), 2 weeks after treatment (T1), 2 months after treatment (T2), and 6 months after treatment (T3)

Key secondary outcome(s))
Unassisted maximum interincisal opening (MIO), including overlap, was measured using a millimeter-scaled ruler at the same time points: before injection (T0), 2 weeks after treatment (T1), 2 months after treatment (T2), and 6 months after treatment (T3)

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Patients aged between 18 and 35 years old with symptoms of unilateral DDwoR with limited mouth opening (≥1 month) mentioned in the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD), maximum assisted opening <40 mm, and restricted mouth opening that interferes with the ability to eat
2. Conservative treatments (pharmacological-physical) failed to improve their symptoms
3. Level pain≥5 on the Numeric Rating Scale (NRS).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Female

Total final enrolment
20

Key exclusion criteria
1. Allergy to dextrose
2. Having parafunctional habits
3. Restriction of mouth opening by spasm muscles or joint adherence
4. Previous exposure to IAI
5. Unwillingness to continue

Date of first enrolment
01/08/2023

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
Syria

Study participating centre

Damascus University
Faculty of Dentistry, Department of Oral and Maxillofacial Surgery
Almazzeh St
Damascus
Syria
20872

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Research organisation

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available on request from Yasser Alsayed Tolibah (yasseralsayedtolibah@gmail.com).
The type of data that will be shared: All data can be shared, including age and outcome measurements.

Dates of availability: by 01/06/2025.
Whether consent from participants was required and obtained: All patients signed an informed consent form that their data would be a part of a scientific study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			21/01/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes