

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
20/01/2025	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
21/01/2025	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
21/01/2025	Musculoskeletal Diseases	<input type="checkbox"/> 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

### Contact name

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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)

## **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 ( $\geq 1$  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  $\geq 5$  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  
Almazeh 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?
<a href="#">Participant information sheet</a>		21/01/2025	No	Yes	
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes