

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effectiveness of neurofacial prolotherapy dextrose on temporomandibular joint disorders

#### Protocol summary

##### Study aim

1- Determining the average pain score and dysfunction score of patients based on visual analog scale in patients with temporomandibular joint (TMJ) disorders in hypertonic dextrose prolotherapy and physiotherapy group before entering the study and then one, three and 6 months after the intervention. 2- Determining the average maximum mouth opening and the presence/absence of click in the joint in patients with TMJ disorders in the group of hypertonic dextrose prolotherapy and physiotherapy, before entering the study and then one, three and 6 months after the intervention.

##### Design

A controlled, cross-over, single-blind, randomized, phase 2 clinical trial on 34 patients. Block randomization was used for randomization.

##### Settings and conduct

The intended study will be conducted in patients referred to Imam Reza (AS) hospital. The patients are divided into two intervention and control groups. It is in the form of 1 session for each involved joint using a 30 size needle and a 3 ml syringe with the combination 0.75 ml of 50% dextrose, 0.75 ml of sterile distilled water and 1.5 ml of 2% lidocaine are injected in the area around the TMJ and in the neurofascial path under ultrasound guidance. In the control group, 10 sessions of routine physiotherapy are performed.

##### Participants/Inclusion and exclusion criteria

Consciously and voluntarily in all patients between 20 and 65 years of age who have TMJ disorders and have no signs of infection, previous surgery, tumor in the target joint, and have a history of diabetes, coagulation or rheumatological disorders, or steroid use within 1 month. Not recent or during pregnancy or breastfeeding.

##### Intervention groups

in the intervention group, hypertonic dextrose solution will be injected and in the control group, physiotherapy will be done.

#### Main outcome variables

the pain; Dysfunction; Joint range of motion with VAS

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220620055227N1**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

##### Registration date

2022-09-03, 1401/06/12

##### Registrant information

##### Name

sepanta hatam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4413 9422

##### Email address

sepanta3v@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2022-12-22, 1401/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effectiveness of neurofacial prolotherapy dextrose ontemporomandibular joint disorders

**Public title**

Evaluation of the effectiveness of neurofacial prolotherapy dextrose ontemporomandibular joint disorders

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with temporomandibular joint disorders  
Informed consent of the patient and willingness to participate in the study

**Exclusion criteria:**

Active infection in the temporomandibular joint  
Pregnancy and breastfeeding  
History of surgery in the joint itself  
A history of fracture or dislocation in the temporomandibular joint  
History of tumor and malignancy in place  
Coagulation disorders  
Use of systemic corticosteroid drugs in the last month  
diabetes  
Systemic rheumatological disorders  
Taking anticoagulant drugs

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **34**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, blocks of 4 are prepared, each block includes 2 patients for the control group and 2 patients for the intervention group. For example, in one block, the first two patients may be placed in the control group and the next two patients in the intervention group. And in another block, the patients may be divided one by one.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Every patient is examined in the first visit by a doctor who is an expert in the field of the disease and is unaware of the patient's therapeutic intervention group, and the follow-up and recording of changes in the examination after the intervention is also recorded by the same doctor. It is the result of the intervention, it is requested not to talk about the treatment done. Also, the analysis of statistical data is done by an analyst who does not know the intervention group of patients.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of AJA University of Medical Sciences

**Street address**

No. 15, azadeh Ave., South Bahar street., west fedos blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1484618386

**Approval date**

2022-06-19, 1401/03/29

**Ethics committee reference number**

IR.AJAUMS.REC.1401.005

**Health conditions studied****1****Description of health condition studied**

Temporomandibular joint pain

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain intensity based on visual analog scale after intervention

**Timepoint**

At the beginning of the study (before the start of the intervention) and 1 month, then 3 and 6 months after the intervention.

**Method of measurement**

Visual analog scale (VAS) questionnaire

**2****Description**

Severity of functional impairment based on visual analog scale after intervention

**Timepoint**

At the beginning of the study (before the start of the intervention) and 1 month, then 3 and 6 months after the intervention.

## Method of measurement

Visual analog scale (VAS) questionnaire

### 3

#### Description

The maximum distance between teethUpper and lower bite that can be done by the patientIt can be done without causing pain, after the intervention.Community Verified icon

#### Timepoint

At the beginning of the study (before the start of the intervention) and 1 month, then 3 and 6 months after the intervention.

#### Method of measurement

Ruler in mm

### 4

#### Description

Additional sound found during opening and closing of the mouth in the temporomandibular joint

#### Timepoint

At the beginning of the study (before the start of the intervention) and 1 month, then 3 and 6 months after the intervention.

#### Method of measurement

During the doctor's examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intended study will be conducted in patients referred to Imam Reza (AS) Hospital. The patients are divided into two intervention and control groups. In the prolotherapy group, the intervention is in the form of 1 session for each involved joint using a measuring needle. 30 and a 3 ml syringe with a combination of 0.75 ml of 50% dextrose, 0.75 ml of sterile distilled water and 1.5 ml of 2% lidocaine is injected in the area around the temporomandibular joint and in the neurofascial path under ultrasound guidance.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: under 10 regular sessions of physiotherapy of the temporomandibular joint area involved by the routine modality of physiotherapy in each session: heat therapy with IR light for 10 minutes, electrotherapy by TENS with an analgesic approach for 5 minutes, US with pulse and high frequency method for 5 minutes. All Therapeutic modalities are the creation of a modern medical engineering company.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Sepanta

##### Street address

Imam Reza hospital, Etemad zade Ave, Fatemi Street, Amirabad

##### City

Tehran

##### Province

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1411718546

##### Phone

+98 21 8609 6350

##### Email

sepanta3v@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Reza Mosaed

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AJA university of medical science Etemad zade Ave, Fatemi Street, Amirabad

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##### Province

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Artesh University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

**Country of origin**  
**Type of organization providing the funding**  
Academic

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Sepanta Hatam  
**Position**  
resident  
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Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available