Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effectiveness of neurofacial prolotherapy dextrose ontemporomandibular 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

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Email address

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
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AJA university of medical science Etemad zade Ave, Fatemi Street, Amirabad
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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

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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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