

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 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

Tehran

Postal code

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

sepanta3v@yahoo.com

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

Phone
+98 21 8609 6350
Email
sepanta3v@yahoo.com

Person responsible for general inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Sepanta Hatam
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
AJA university of medical science Etemad zade Ave,
Fatemi Street, Amirabad
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
sepanta3v@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Sepanta Hatam
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
AJA university of medical science Etemad zade Ave,
Fatemi Street, Amirabad
City
Tehran
Province
Tehran
Postal code
1411718541

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Sepanta Hatam
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
AJA university of medical science Etemad zade Ave,
Fatemi Street, Amirabad
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
sepanta3v@yahoo.com

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