

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of diode laser with transcranial direct current stimulation(TDCS) in reducing symptoms in patients with temporomandibular disorders (TMD)

Protocol summary

Study aim

Comparison of the effect of diode laser with transcranial direct current stimulation(TDCS) in reducing symptoms in patients with temporomandibular disorders (TMD)

Design

The sample size of 34 people will be randomly divided into two groups (using a random number table) and will be treated with laser or TDCS. There is no possibility of blindness.

Settings and conduct

34 people with TMD will be selected according to the inclusion criteria by referring to Shahid Sadoughi Dental School of Yazd. Before studying, informed consent will be filled by the samples. In the laser group, 9 sessions of laser therapy using diode laser during 3 weeks (3 times a week) and in the TDCS group, treatment will be performed by one person in 5 sessions for 5 consecutive days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients 40-18 years old 2) Have vague or obvious pain in the temporomandibular joint for at least 2 months (score 4 or higher on the VAS scale). 3) Have at least one of the following two symptoms. 1. Sensitivity to the touch of one or more masticatory muscles 2. Mandibular restriction on opening 4) Fill in the informed consent of the patient to enter the study 5) Do not have a history of jaw trauma. 6) Do not have a history of joint disease and rheumatoid arthritis. 7) Do not currently be treated for TMD.

Intervention groups

We have two intervention groups, one group will be treated with laser and the other group with TDCS.

Main outcome variables

Determination and comparison of mean pain score, masticatory muscle tenderness, maximum range of mouth opening before and after treatment in the two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210321050751N3**

Registration date: **2022-09-27, 1401/07/05**

Registration timing: **prospective**

Last update: **2022-09-27, 1401/07/05**

Update count: **0**

Registration date

2022-09-27, 1401/07/05

Registrant information

Name

Soghra Yassaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 6975

Email address

syassaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of diode laser with transcranial direct current stimulation(TDCS) in reducing symptoms in patients with temporomandibular disorders (TMD)

Public title

Comparison of the effect of diode laser with transcranial direct current stimulation(TDCS) in reducing symptoms in patients with temporomandibular disorders (TMD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) Patients 40-18 years old 2) Have vague or obvious pain in the temporomandibular joint for at least 2 months (score 4 or higher on the VAS scale). 3) Have at least one of the following two symptoms.1. Sensitivity to the touch of one or more masticatory muscles2. Mandibular restriction on opening 4) Fill in the informed consent of the patient to enter the study 5) Do not have a history of jaw trauma. 6) Do not have a history of joint disease and rheumatoid arthritis. 7) Do not currently be treated for TMD.

Exclusion criteria:

1. Any illness or trauma that occurs after the start of the study for the samples and affects the rate of TMD symptoms. 2.Taking drugs such as cartilage-building drugs and NSAIDs 3.Lack of cooperation in continuing the study to complete the treatment sessions

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

More than 1 sample in each individual

Number of samples in each individual: **2**

TMJ joint and masticatory muscles of each sample before and after the intervention

Randomization (investigator's opinion)

Randomized

Randomization description

The design of the study is done before and after (before & after). The samples are randomly divided into two groups of 17 and one group will be treated with laser and the other group with TDCS. In this study, a simple randomization method is used. It is an individual randomization unit and the randomization tool is the use of a random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Shahid Sadoughi University of Medical Science

Street address

Yazd. Dahe fajr Boulevard. Imam Reza Street.Shahid Sadoughi University of Medical Science

City

Yazd

Province

Yazd

Postal code

8914881167

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1401.014

Health conditions studied

1

Description of health condition studied

Temporomandibular joint disorders (TMD)

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Pain score changes

Timepoint

Before treatment, 1 and 3 months after treatment

Method of measurement

VAS

2

Description

masticatory muscle tenderness changes

Timepoint

Before treatment, 1 and 3 months after treatment

Method of measurement

1,2,3,4

3

Description

Changes in the range of maximum mouth opening

Timepoint

Before treatment, 1 and 3 months after treatment

Method of measurement

mm

Secondary outcomes**1****Description**

Patient satisfaction score of treatment

Timepoint

after treatment

Method of measurement

questionnaire, Contains questions about improving function, jaw sounds, sleep disorders, etc. after treatment

Intervention groups**1****Description**

Intervention group: In the laser group, 9 sessions of laser therapy using diode laser (980 nm, 100 mW) will be performed during 3 weeks (3 times a week).The diode laser is applied in three areas in the TMJ joint, temporalis muscle and gonial angle with a 90 degree angle in contact with the skin and for 10 seconds at each point in 3 points with a distance of 4 mm.

Category

Treatment - Other

2**Description**

Intervention group: In the TDCS group, treatment will be performed in 5 sessions for 5 consecutive days.The TDCS device consists of anode and cathode electrodes, which are connected to an energy source that produces direct current (DC). Two electrodes, one positive pole and the other negative pole, are placed on the head through a sponge pad that is moistened with a conductive solution such as washing serum. They take Passing a weak current to the brain between two electrodes, where the current enters the brain from the anode, passes through the tissue and exits from the cathode, creates changes in the brain. The anode pole in this method leads to an increase in excitability and pole Cathode reduces cortical excitability and the duration of stimulation is up to 20 minutes

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Orthodontics Department of Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Parisa Mohsenzade

Street address

Yazd. Dahe fajr Boulevard. Imam Reza Street.Shahid Sadoughi University of Medical Science

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3625 5813

Email

samat@ssu.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Department of Orthodontics,Shahid Sadoughi School of Dentistry,Yazd

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3625 5813

Email

mmirzaei@ssu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Parisa Mohsenzade

Position

Orthodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Yazd. Dahe fajr Boulevard. Imam Reza Street. Shahid
Sadoughi University of Medical Science

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 34 3428 4157

Email

p.mzade75tums@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Parisa Mohsenzade

Position

Orthodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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p.mzade75tums@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Parisa Mohsenzade

Position

Orthodontics resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After unidentifying ,it is possible to share all variables of patients.

When the data will become available and for how long

Start the access period 6 months after publishing the results.

To whom data/document is available

Researchers working in academic and scientific institutions and valid scientific research journals.

Under which criteria data/document could be used

In order to use the documents of this study for other studies and researches to apply the results and efficiency of modern TMD treatments

From where data/document is obtainable

Responsible person in this field :parisa mohsenzade
,email address : p.mzade75tums@gmail.com

What processes are involved for a request to access data/document

The applicant can send his request to the above-mentioned email address his/her introduction and the reason for the request and receive the information as soon as possible (finally within 7-10 days)

Comments