

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 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 Nsaid 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

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**Province**

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**Postal code**

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**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

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**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**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Parisa Mohsenzade

**Position**

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**Latest degree**

Medical doctor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

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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**