Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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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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
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Person responsible for scientific inquiries

Contact
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Parisa Mohsenzade
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Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Medical doctor
Other areas of specialty/work
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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