

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 2026

**Investigating the quality of life and pain and maximum mouth opening in patients with temporomandibular disorders referring to the jaw and face pain clinic of Semnan Faculty of Dentistry with the complementary treatment of laser acupuncture.**

### Protocol summary

#### Study aim

Investigating the effect of complementary treatment of temporomandibular disorders with laser acupuncture on improving quality of life

#### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 20 patients. Block was used for randomization.

#### Settings and conduct

Study done in the physiotherapy clinic of Semnan and using low power diode laser machine. The study is double-blind and the patients do not know which group they are in. A dental student, who is not aware of the groupings, measures the variables before and after the study and Executive officer of study inform the physiotherapist about the groupings for treatment, which is laser treatment for the treatment group or only the guiding light of the device for the control group.

#### Participants/Inclusion and exclusion criteria

inclusion criteria: 1- Patients with a history of pain 2- Restriction in jaw movements 3\_ Jaw sound 4- Deviation during opening and closing the mouth exclusion criteria: 1- Patients with a history of acute trauma 2- Patients who have been treated for temporomandibular joint disorders in the last month. 3- Any pain of other origin

#### Intervention groups

For the target group of 10 patients, laser therapy with LUMIX 2 HFPL low power diode laser device made in Italy with wavelength nm810, output power mw500 and energy density j/cm<sup>2</sup> 21, frequency 13 kHz, output energy J 16.4 and modulation 100% with continuous waveform to Duration of 3 minutes in each acupuncture point, which is 30 minutes for a total of 10 points. The treated points include: GB20, SI19, ST6, ST7, LI4, which will be treated bilaterally. 2- For the placebo group of 10 patients, only the guiding light of the device will be used

as laser acupuncture in the same areas and frequency and time as the first group .

#### Main outcome variables

Increasing the quality of life, reducing pain, increasing the maximum opening of the mouth

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230812059121N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

#### Registration date

2023-09-18, 1402/06/27

#### Registrant information

##### Name

Mohaddeseh Davari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3333 5363

##### Email address

mdavari@semums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-08-14, 1402/05/23

**Expected recruitment end date**

2024-08-13, 1403/05/23

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the quality of life and pain and maximum mouth opening in patients with temporomandibular disorders referring to the jaw and face pain clinic of Semnan Faculty of Dentistry with the complementary treatment of laser acupuncture.

**Public title**

Investigating the effect of laser acupuncture on the quality of life of patients with temporomandibular disorders

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with a history of pain with VAS $\geq$ 4 in masticatory muscles and/or temporomandibular joint during jaw movements or function (TMD muscle disorders (Class Ia, Ib) or anterior displacement of the disc with or without return (Class IIa, IIb) or arthralgia (Class IIIa) based on (RDC/TMD) Limitations in jaw movements (mouth opening < 40 mm or side movements < 8 mm) Jaw sound while opening and closing the mouth Deviation during opening and closing the mouth

**Exclusion criteria:**

Patients with a history of acute trauma Patients who have been treated for temporomandibular joint disorders in the last month Any pain with other origins such as decayed teeth, impacted teeth, other pathological lesions or neurological disorders in the head and neck area People with congenital and neoplastic diseases in the TMJ range People with joint diseases such as osteoarthritis and rheumatoid arthritis or suffering from hypermobility syndrome Uncontrolled systemic problems with disability (ASA II or higher) including diabetes, thyroid disease, kidney disease, epilepsy and people with cerebrovascular problems People with bleeding diseases or users of anticoagulants Users of corticosteroid drugs Cardiac patients or those with a pacemaker Pregnant or breastfeeding mothers Patients with psychiatric disorders such as severe depression and psychosis Patients with any severe orthognathic deformities Patients with posterior edentulousness

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: 20

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the first stage, patients are included in the study by meeting the criteria for entering the study. Therefore, our sampling method is easy at this stage. In the second stage, they are divided into two groups A and B using the block randomization method. Then, in the third step, using the table of random numbers, we determine which group will receive treatment and which group will receive placebo.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients are informed that this plan is a study and includes two treatment and control groups, but they do not know about their group, and a dental student measures the variables of the study before and after the treatment, who is blind to the groupings. The executive officer of the plan informs the physiotherapist about the groups to use the laser for the treatment group and the guiding light of the device for the control group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

**Street address**

dental clinic.hefdah shahrivar Blvd

**City**

semnan

**Province**

Semnan

**Postal code**

35187-94431

**Approval date**

2023-08-17, 1402/05/26

**Ethics committee reference number**

IR.SEMUMS.REC.1402.091

**Health conditions studied****1****Description of health condition studied**

temporomandibular disorders

**ICD-10 code**

M26.60

**ICD-10 code description**

Temporomandibular joint disorder, unspecified

**Category**

Treatment - Devices

**Primary outcomes****1****Description**

quality of life

**Timepoint**

The beginning and end of the study and One month after the last treatment session

**Method of measurement**

questionnaire

**2****Description**

Maximum mouth opening

**Timepoint**

The beginning and end of the study and One month after the last treatment session

**Method of measurement**

Ruler with millimeter division

**3****Description**

pain

**Timepoint**

The beginning and end of the study and One month after the last treatment session

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

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

Intervention group: Laser therapy with LUMIX 2 HFPL low power diode laser machine made in Italy with wavelength nm810, output power mw500 and energy density j/cm<sup>2</sup> 21, frequency 13 kHz, output energy J 16.4 and modulation 100% with continuous waveform for 3 minutes. It takes 30 minutes for each acupuncture point, for a total of 10 points. The points under treatment include: GB20, SI19, ST6, ST7, LI4, which will be treated bilaterally. Both groups visit twice a week for a total of 10 sessions.

**Category**

Treatment - Devices

**2****Description**

Control group: Only the guiding light of the device will be used as laser acupuncture in the same areas and with the same frequency and time as the first group.

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

Semnan Faculty of Dentistry

**Full name of responsible person**

Maryam Shirnasab

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shirin1998f@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Rasool Bagheri

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Rasool.bagheri@ymail.com

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

No

**Title of funding source**

Faculty of Physiotherapy

**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**

Semnan University of Medical Sciences

**Full name of responsible person**

Rasool Bagheri

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Nahid Karbasi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Maryam Shirnasab

**Position**

student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Province**

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**Postal code**

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**Phone**

+98 991 768 2789

**Email**

shirin1998f@gmail.com

**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**

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

**Title and more details about the data/document**

Information on the main outcome is shared

**When the data will become available and for how long**

شروع دوره دسترسی 4 ماه پس از چاپ نتایج

**To whom data/document is available**

محققین شاغل در موسسات دانشگاهی و علمی

**Under which criteria data/document could be used**

It can be used by mentioning the source

**From where data/document is obtainable**Maryam Shiransab with email  
address:shirin1998f@gmail.com**What processes are involved for a request to access data/document**

Accept the request until 2 months later

**Comments**