Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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/cm2 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≥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

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/cm2 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.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Semnan Faculty of Dentistry
Full name of responsible person
Maryam Shirnasab
Street address
hefdah shahrivar
City
semnan
Province
Semnan
Postal code
35187-94431
Phone
+98 991 768 2789
Email
shirin1998f@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Rasool Bagheri
Street address
hefdah shahrivar
City
semnan
Province
Semnan
Postal code
35187-94431
Phone
+98 991 768 2789
Email
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
Street address
hefdah shahrivar
City
semnan
Province
Semnan
Postal code
35187-94431
Phone
+98 910 073 7438
Email
Rasool.bagheri@ymail.com

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
Dentistry
Street address
Hefdeh Shahrivar Street
City
semnan
Province
Semnan
Postal code
3518794431
Phone
+98 913 397 8074
Email
sov.karbasi@gmail.com

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
Street address
Hefdeh Shahrivar Street
City
semnan
Province
Semnan
Postal code
35187-94431
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 4ماه 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