

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of thermotherapy and low power laser treatment in patients with (TMD)Temporo mandibular joint disorder

Protocol summary

Study aim

Comparison of thermotherapy and low power laser treatment in patients with (TMD)Temporo mandibular joint disorder

Design

Clinical trial with parallel intervention groups is randomized, without blinding and random sampling method. The randomization method is simple and uses the random numbers chart. 33 people were divided into three groups. Laser, diathermy treatment and hot pack will be used for the first, second and third groups, respectively, with the same drug. Finally, the amount of pain and the amount of mouth opening in the groups will be measured and compared.

Settings and conduct

The study will be performed in the maxillofacial surgery department of Tabriz Dental School. Three different groups of patients with Temporo mandibular joint disorder will be treated with three different treatments including low power laser, diathermy and hot pack for 12 sessions (two sessions per week). The severity of the pain and the amount of mouth opening will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. People with myofascial orofacial pain 2. Restricted mouth opening 3. Aratralgic 4. Difficulty chewing 5. Patients with pain in the masticatory and joint muscles, whether during compression or during jaw movements due to a disorder of the temporomandibular joint. Withdrawal conditions: 1. Abnormal skeletal occlusions (class II and class III occlusion) 2. Systemic disorders affecting the temporomandibular joint 3. Patients who have received analgesic or anti-stress drugs during the previous two weeks 4. Suspected pulpitis teeth 5. Children 6. Pregnant and lactating women 7. Patients with epilepsy

Intervention groups

Intervention group 1: Laser treatment Intervention group 2: Diathermy treatment Intervention group 3: Hot pack treatment

Main outcome variables

The amount of pain The amount of mouth opening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201124049483N1**

Registration date: **2020-11-27, 1399/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-27, 1399/09/07**

Update count: **0**

Registration date

2020-11-27, 1399/09/07

Registrant information

Name

Reza Khorshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7314

Email address

dr_khorshidi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-20, 1399/08/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of thermotherapy and low power laser treatment in patients with (TMD)Temporo mandibular joint disorder

Public title

Comparison of two different treatments in patients with jaw disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with myogenic orofascial pain Restrict mouth opening Aratralgic Difficulty chewing Patients with pain in the masticatory and joint muscles

Exclusion criteria:

Abnormal skeletal occlusions (class II and class III occlusion) Systemic disorders that affect the temporomandibular joint Patients who have received analgesic or anti-stress medications in the past two weeks Teeth suspected of pulpitis Children Pregnant and lactating women Patients with epilepsy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 33

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is random among the people referring to the maxillofacial surgery department of Tabriz Dental School. The randomization method is simple and the unit is individual. Our tool for randomization is the randomized number chart. Furthermore, the allocation of treatment to patients will be done Randomly. To do this, the types of treatment are identified with code A (diathermy) , B (laser) and C(hot pack) , and then will be placed in sealed envelopes and will be stirred. Then they are randomly taken out of the bag and after observing the code, the treatment will be given to the patient. None of the patients will be informed about another patient's treatment.

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**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-11-24, 1399/09/04

Ethics committee reference number

IR.TBZMED.REC.1399.799

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

Temporomandibular joint disorder

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

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

The amount of pain

Timepoint

Before and after the study

Method of measurement

Visual Analogue Scale

2**Description**

The amount of mouth opening

Timepoint

Before and after the study

Method of measurement

10 cm ruler calibrated in millimeters

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Laser group: Laser treatment will be performed through a low-power laser device available in Imam Reza Hospital in Tabriz. The patient will be treated for 12 sessions. In this study, a low-power gallium aluminum arsenide GaAlAs METRON laser made in Australia was used using a pen applicator with a cross-sectional area of one centimeter of radiation. The device was calibrated by the engineering company before conducting the research. The specifications of the laser used in this research were as follows: Wavelength = 810 nm Energy density = J / cm² 5 power = mw 100 time = 50 seconds are treated with laser anywhere. We place the probes of the device based on the trigger points and pain places in the desired location. We will place the Red probe on the joint and the INFRARED Scanner on the trigger points in the masticatory muscles.

Category

Treatment - Devices

2

Description

Intervention group: Diathermy group: We place the electrodes of the device in the points of pain and joint. To prevent skin burns between the electrode and the body, we use special oils. The current between the electrodes warms the tissue in the body and induces its therapeutic effects in this way. The patient will be treated for 12 sessions.

Category

Treatment - Devices

3

Description

Intervention group: Hot Pack Group: By bending the piece inside the hot pack, the liquid inside the bag slowly becomes solid and generates high heat for about 15 minutes. To reuse the hot pack bag, it should be placed in hot water for about 5 to 10 minutes so that the material inside the bag becomes liquid again, and you can use the bag again whenever you want. The bag is placed on the spot for ten minutes. The patient will be treated for 12 sessions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Surgery, School of Dentistry, University of Tabriz

Full name of responsible person

Reza Khorshidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Prof. Mohammad Samiei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Reza Khorshidi

Position

Lecturer

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

lecturer

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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