Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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
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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