Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative Evaluation of Two Methods :Low Level Laser and Laser Acupuncture In Relieving Pain In Patients With Temporomandibular Disorders (A Randomized Clinical Trial)

Protocol summary

Summary

The aim of this study is to comparative the efficacy of low-level of laser therapy (LLLT) and laser acupuncture in the management of pain in patients with temporomandibular joint disorders (TMD). In this randomized, double-blind clinical trial, 45 patients with TMD Will be divided randomly in three groups as follows: laser, laser acupuncture, and placebo. In the laser group, a pulsed 810-nm low-level laser (average power 200 mW) will be applied on the painful points twice a week for a 5-week period. In the placebo group, the treatment will be the same as that in the laser group, but without energy output. In the laser acupuncture group, a pulsed 810-nm low-level laser (average power 200 mW) will be used on acupuncture points (LI4, ST6, ST7) twice a week for a 5-week period. .The patients will be evaluated before laser therapy (T1), after five sessions of laser application (T2), at the end of treatment (T3), and 1 month after the last session (T4). Pain will be measured by using 10-cm Visual Analog Scale (VAS) scores and Maximum mouth opening. Lateral and protrusive mandibular movements , will be measured by the caliber of digitalis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010131710N1**
Registration date: **2017-06-01, 1396/03/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-01, 1396/03/11

Registrant information

Name

Naeeme Daghestani

Name of organization / entity

Mashhad University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Science

Expected recruitment start date

2016-11-28, 1395/09/08

Expected recruitment end date

2018-11-29, 1397/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of Two Methods :Low Level Laser and Laser Acupuncture In Relieving Pain In Patients With Temporomandibular Disorders (A Randomized Clinical Trial)

Public title

Laser Therapy In Relieving Pain In Patients With Temporomandibular Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with myogenic orofacial pain; limited mouth opening ; arthralgia ; difficulty chewing ; patients with pain in the myofascial and joint area and either during palpation or jaw movements Exclusion Criteria: Systemic diseases that affect temporomandibular joint ; patients who have received analgesics or anti-stress drugs during the last two weeks ; teeth pulpitis ; children ; pregnant women and nursing mothers ; epilepsy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad Dental School

Street address
School of Dentistry, Vakilabad Blvd, Mashhad, Iran

City
Mashhad

Postal code
91735

Approval date
2016-12-28, 1395/10/08

Ethics committee reference number
IR.mums.sd.REC.1394.191

Health conditions studied

1

Description of health condition studied
Temporomandibular Disorders

ICD-10 code
K07.6

ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
pain

Timepoint
before treatment, third week,fifth week, tenth week

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
measure of mouth opening

Timepoint
before treatment, third week,fifth week, tenth week

Method of measurement
caliber of digitalis

2

Description
measure of lateral and protrusive mandibular movements

Timepoint
before treatment, third week,fifth week, tenth week

Method of measurement
caliber of digitalis

Intervention groups

1

Description
In the laser group, a pulsed 810-nm low-level laser (average power 200 mW) are used on painful points two times a week for 5 weeks

Category
Treatment - Other

2

Description
In the laser acupuncture group, a pulsed 810-nm low-level laser (average power 200 mW) are used on acupuncture points (LI4 , ST6 , ST7) two times a week for 5 week

Category
Treatment - Other

3

Description
In the placebo group, the treatment is the same as that in the laser group, but without energy output

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad School of Dentistry
Full name of responsible person
Dr Azam Madani
Street address
Mashhad School of Dentistry
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research and Technology Department of Mashhad University of Medical Sciences
Full name of responsible person
Dr Azam Madani
Street address
Mashhad Dentistry School
City
Mashhad
Grant name
951115
Grant code / Reference number
951115
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Technology Department of Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty