Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Randomized Control Trial of Comparing low level Helium-Neon laser and pharmacological therapy in pain relief of patients with temporomandibular disorders

Protocol summary

Summary

About 20 to 30% of adults suffer from temporomandibular joint disorder, out of which 90% seek therapy for symptoms relating to temporomandibular joint. Non-surgical treatment is the first step in the treatment of patients with joint pain and dysfunction. Common therapeutic methods to reduce pain and dysfunction of temporomandibular joint are: drug therapy, laser therapy, physical therapy, etc. While previous studies have addressed the effects of drug therapy and laser therapy on patients with temporomandibular joint disorders, none of them have used Helium-Neon laser. Additionally, no comparison has been made between the effects of this method and drug therapy. Consequently, the aim of the present study is to compare the effects of laser and drug therapy in patients with temporomandibular joint disorders. This randomized control trial was carried out on a sample of 72 patients who met the inclusion criteria for the study. The patients were randomly divided into two groups of drug therapy and laser therapy. Inclusion criteria was patients within the age of 20 to 45 who had at least two of the following symptoms: 1.Dysfunction of masticatory muscles; 2.Restrictive jaw movements; 3.Clicking sound; and exclusion criteria included: 1. Any kind of systemic illness; 2.Any kind of supportive therapies like drug therapy and physical therapy; Evaluation of pain was done using Visual Analog Scale and Active Range Of Motion. Both methods were effective in the treatment of temporomandibular joint disorders; however, laser showed significant decrease in the recovery process.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412235565N3**

Registration date: **2015-01-07, 1393/10/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-07, 1393/10/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2014-04-19, 1393/01/30

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Control Trial of Comparing low level Helium-Neon laser and pharmacological therapy in pain relief of

patients with temporomandibular disorders

Public title
Comparison of low level Helium-Neon laser and pharmacological therapy in patients with temporomandibular disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients between 20-45; Dysfunction of masticatory muscles; Restrictive jaw movements; Clicking sound; Sensitivity to palpation at Temporomandibular Joint. Exclusion criteria: Any kind of systemic illness; Any kind of supportive therapies like drug therapy and physical therapy; Age limits other than 20 to 45.
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Rafsanjan University of Medical Sciences
Street address
Emam Ali Blvd, Rafsanjan University of Medical Sciences
City
Rafsanjan
Postal code
Approval date
2014-04-15, 1393/01/26
Ethics committee reference number
93015

Health conditions studied

1

Description of health condition studied
temporomandibular disorder
ICD-10 code
k07.6
ICD-10 code description
Other enteropathic arthropathies

Primary outcomes

1

Description
Evaluation of the amount of pain
Timepoint
Immediately after treatment, 1 week, two week and 4 weeks after trearment
Method of measurement
visula analog scale

2

Description
Evaluation of Clicking sound
Timepoint
Immediately after treatment, 1 week, two week and 4 weeks after trearment
Method of measurement
palpation of patients ear and using sthetoscope

3

Description
Restrictive mouth movements
Timepoint
Immediately after treatment, 1 week, two week and 4 weeks after trearment
Method of measurement
Using a ruler

4

Description
Tenderness
Timepoint
Immediately after treatment, 1 week, two week and 4 weeks after trearment
Method of measurement
palpation of masseter and temporalis muscles and temporomandibular joint

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: using low power Helium-Neon laser in patients with Temporomandibular joint disorder
Category
Treatment - Other

2

Description
Control: Using the usual drug therapy to relieve the symptoms in patients with Temporomandibular joint disorder
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan Dental School
Full name of responsible person
Dr Ali Peymani
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Sponsors / Funding sources

1

Sponsor
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Rafsanjan University of Medical Sciences
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Dr Ali Peymani
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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
Rafsanjan 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

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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