

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Ali Peimani

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 39 1822 0008

Email address

a_peymani@rums.ac.ir

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 treatment

Method of measurement

visula analog scale

2

Description

Evaluation of Clicking sound

Timepoint

Immediately after treatment, 1 week, two week and 4 weeks after treatment

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 treatment

Method of measurement

Using a ruler

4

Description

Tenderness

Timepoint

Immediately after treatment, 1 week, two week and 4 weeks after treatment

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

Street address

West Mofatteh Blvd, Rafsanjan Dental School

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Ali Peymani

Street address

Rafsanjan Dental School

City

Rafsanjan

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

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Ali Peymani

Position

Assistant Professor

Other areas of specialty/work

Street address

Rafsanjan Dental School

City

Rafsanjan

Postal code

Phone

+98 34 3428 0030

Fax

Email

alipeimani2001@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Ali Peymani

Position

Assistant Professor of Oral and Maxillofacial Surgery

Other areas of specialty/work

Street address

Rafsanjan Dental School

City

Rafsanjan

Postal code

Phone

+98 34 3428 0030

Fax

Email

alipeimani2001@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Sepideh Assar

Position

Post graduate student of Oral and Maxillofacial Pathology

Other areas of specialty/work

Street address

Shiraz Dental School

City

Shiraz

Postal code

Phone

+98 71 3623 1559

Fax

Email

sepideh1986@yahoo.com

Web page address

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