

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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## Person responsible for scientific inquiries

### Contact

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#### Position

Assistant Professor of Oral and Maxillofacial Surgery

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## 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

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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*