

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Low level laser therapy as an adjunctive technique in the treatment of temporomandibular disorders

Protocol summary

Summary

This study investigated the efficacy of low-level laser therapy (LLL) as an adjunctive technique for the management of temporomandibular joint disorders. In a double-blind clinical trial, 30 patients with TMD were randomly divided into laser, sham laser and no laser groups. Occlusal splint fabricated for all patients. The patients in the laser group received irradiation from an 980nm which was applied on four points around the TMJs and on painful muscles two times a week for 4 weeks, in the sham laser group the treatment was the same as that in the laser group, but with laser simulation and in the third group patient just received splint. All patients were subjected to clinical examination using Helkimo Dysfunction Index (HDI) to assess the degree of TMD before and after treatment. Inclusion criteria: patients with pain in muscles, TMJ, click exclusion criteria: intracapsular disorders, anatomical disorders, Arthritis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031016933N1**
Registration date: **2014-10-09, 1393/07/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-09, 1393/07/17

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-07-05, 1393/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Low level laser therapy as an adjunctive technique in the treatment of temporomandibular disorders

Public title

Laser effectiveness on the pain and masticatory performance of patients with TMD

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with pain in muscles, TMJ, click
Exclusion criteria: intracapsular disorders, anatomical disorders, Arthritis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Science

Street address
Shiraz University of Medical Science, Zand Street,
Shiraz, Iran.

City
Shiraz

Postal code
14336-71348

Approval date
2014-02-22, 1392/12/03

Ethics committee reference number
CT_P_92_5100

Health conditions studied

1

Description of health condition studied
Temporomandibular Joint Disorders

ICD-10 code
K07.6

ICD-10 code description
Temporomandibular Joint Disorders

Primary outcomes

1

Description
TMJ pain

Timepoint
Before splint therapy and laser application, after splint
therapy and laser application

Method of measurement
Helkimo index

2

Description
Muscle pain

Timepoint
Before splint therapy and laser application, after splint
therapy and laser application

Method of measurement
Helkimo index

3

Description
Motion index

Timepoint
Before splint therapy and laser application, after splint
therapy and laser application

Method of measurement
Helkimo index

4

Description
TMJ function

Timepoint
Before splint therapy and laser application, after splint
therapy and laser application

Method of measurement
Helkimo index

5

Description
Pain on movement of mandible

Timepoint
Before splint therapy and laser application, after splint
therapy and laser application

Method of measurement
Helkimo index

Secondary outcomes

empty

Intervention groups

1

Description
Sham laser in control group

Category
Treatment - Devices

2

Description
No laser in control group

Category
Treatment - Devices

3

Description
Laser in intervention group

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Dentistry of Shiraz University of Medical Sciences

Full name of responsible person

mohammad bayani Postgraduate Student in Prosthodontics

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School of Dentistry, Shiraz University of medical Sciences , Ghasrodasht Street , Qom Abad , Shiraz , Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University Of Medical Sciences

Full name of responsible person

Basir Hashemi

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Shiraz University of Medical Science, Zand Street, Shiraz, Iran.

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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

Shiraz 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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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>