

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**The clinical trial to compare the effect of laser therapy associated with drug therapy on relieving the most common orofacial pains in patients who have trigeminal neuralgia, atypical facial pain and myofascial pain dysfunction syndrome**

### Protocol summary

#### Summary

Objectives: The purpose of this study is to evaluate the effect of low level diode (GA-AS) laser (850-980nm) with the frequency of 3000HZ and dose of 6.3 J/cm<sup>2</sup> during 10 section of laser therapy on the orofacial pain of 60 patients. Design: This study is a randomized triple blind clinical trial with active (positive) concurrent control which is done on the phase of 2 of clinical trial. Setting and conduct: The patients in the group of case receive drug therapy in association with Low Level Laser therapy; however, the patients in the control group are treated with drug and sham laser. The patients and all of the operators of this study are not aware of the type of laser which is used for each patient. Participants including major eligibility criteria: The patients who have the criteria of Trigeminal Neuralgia, Atypical Facial Pain and Myofascial Pain Dysfunction Syndrome and the patients who have not a good response to routine drug therapy can enter the study; however, the patients who have a good response to previous drug therapy and the pregnant women are excluded. Intervention: In this study we evaluate the effect of low level diode (GA-AS) laser (850-980nm) with the frequency of 3000HZ and dose of 6.3 J/cm<sup>2</sup> during 10 section of laser therapy on the orofacial pain of 60 patients. Main outcome: In order to evaluate the effect of laser therapy Visual Analogue Scale is used before and after intervention and in the period of 2 -4 months after intervention.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201201018585N1**  
Registration date: **2012-02-01, 1390/11/12**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2012-02-01, 1390/11/12

#### Registrant information

##### Name

Fatemeh Lavaee

##### Name of organization / entity

Shiraz Dental School

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1631 9309

##### Email address

lavaee@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

#### Expected recruitment start date

2010-01-20, 1388/10/30

#### Expected recruitment end date

2012-02-29, 1390/12/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The clinical trial to compare the effect of laser therapy associated with drug therapy on relieving the most common orofacial pains in patients who have trigeminal neuralgia, atypical facial pain and myofascial pain

dysfunction syndrome

**Public title**

The effect of laser therapy on the orofacial pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Having the criteria of each of the pains including Trigeminal Neuralgia, Atypical Facial Pain and Myofascial Pain Dysfunction Syndrome: The patients who have not a good response to routine drug therapy:

Exclusion criteria: the patients who have a good response to previous drug therapy: The pregnant women

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics committee of Shiraz university of Medical Science

**Street address**

Zand street, Shiraz, Central building of Fars University of Medical Science

**City**

Shiraz

**Postal code****Approval date**

2011-12-19, 1390/09/28

**Ethics committee reference number**

CT-90-5886

**Health conditions studied****1****Description of health condition studied**

Trigeminal Neuralgia

**ICD-10 code**

G50.0

**ICD-10 code description**

Diseases of the nervous system, disorders of 5th cranial nerve

**2****Description of health condition studied**

Myofascial Pain Dysfunction Syndrome

**ICD-10 code**

M62.4

**ICD-10 code description**

Diseases of the musculoskeletal system and connective tissue, Other disorders of muscle

**3****Description of health condition studied**

Atypical Facial Pain

**ICD-10 code**

G50.1

**ICD-10 code description**

Nerve, nerve root and plexus disorders, disorders of 5th cranial nerve

**Primary outcomes****1****Description**

The amount of pain

**Timepoint**

Before and after intervention and 2-4 months after intervention

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

The metabolite of serotonin-like 5-hydroxy indole acetic acid (5-HIAA)

**Timepoint**

Before, after, 2-4 month after intervention

**Method of measurement**

24-hour urine

**Intervention groups****1****Description**

Intervention group: 10 sessions of Low level laser therapy (LLLT) + standard drug therapy of their pain. The type of laser is Ga-AS (Device model: DLT 101) with pulse mode-

mod II of exposure. The time of exposure is 5 min with frequency of 3000 HZ, 5 watt potency. The wave length of device is 980 -850 nm. According to these properties the total dose is 6.3 J/cm<sup>2</sup>. The Laser is applied on the trigger point if it exists, if not the operator will choose some trigger points on the pathway of pain.

#### Category

Treatment - Other

## 2

#### Description

Control group: Sham laser + Standard drug therapy of their pain  
Diagnosis of orofacial pain: Trigeminal neuralgia (TN) is the most common of the cranial neuralgias and chiefly affects individuals older than 50 years of age. It has characteristic clinical feature which include episode of intense shooting, stabbing pain that lasts for a few seconds and then completely disappear. The pain has electric like quality and is unilateral except in few cases. TN is precipitated by nonnoxious stimulation like a light touch on a trigger zone. Presence of trigger point is pathognomic for TN. The most common treatment recommended for TN is as followed: Carbamazepin, Gabapentin, Lamotrigine, Phenytoin, Oxcarbazepin, Valproic acid, Topiramate. Other effective drugs other than anticonvulsants are Clonazepam, Baclofen, Diazepam, Pimozide. IHS system, use the term facial pain not fulfilling other criteria to describe patients with atypical facial pain. This pain is a chronic pain syndrome which does not fall into other diagnostic categories. The major manifestation of AFP is a constant dull, aching pain without an apparent cause. It's not paroxysmal and doesn't precipitate by activity and doesn't follow any anatomic pattern. Analgesics have no effect on AFP but tricyclic antidepressants can reduce the pain. It seems that psychotherapy has an important role in AFP treatment. Myofascial pain dysfunction syndrome (MPDS) is a muscular pain due to increased load and muscular hyperactivity. MPDS manifests as a dull pain with a tender trigger point in muscles, tendon and their fascias which are tender on palpation. The referral pain and autonomic symptoms can be detected on palpation of the trigger zone. The muscle relaxants (methocarbamol) and NSAIDs can relieve the symptoms.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz Dental School -Oral Medicine Department

##### Full name of responsible person

Dr. Fatemeh Lavaee

##### Street address

Ghasrdasht Street, Shiraz, Oral Medicine Department, Shiraz Dental School

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Gholam Reza Hatam

##### Street address

Zand street, Shiraz, Central building of Fars University of Medical Science

##### City

Shiraz

#### Grant name

ردیف بودجه طرح های تحقیقاتی

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, 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

Shiraz Dental School

##### Full name of responsible person

Dr. Fatemeh Lavaee

##### Position

The assistant of oral medicine

##### Other areas of specialty/work

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## Person responsible for scientific

## **inquiries**

### **Contact**

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**Other areas of specialty/work**

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## **Person responsible for updating data**

### **Contact**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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**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*