

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/cm² 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/cm² 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

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Iran (Islamic Republic of)

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+98 71 1631 9309

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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/cm². 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, Lamotrigin, 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

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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

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Full name of responsible person

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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