Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 trigeminel neuralgia, atypical facial pain and myofacial pain dysfunction syndrome

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the effect of low level diod(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 Myofacial 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 diod(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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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 trigeminel neuralgia, atypical facial pain and myofacial 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 Trigeminel Neuralgia, Atypical Facial Pain and Myofacial 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
Myofacial Pain Dysfunction Syndroms
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 metabolit of serotoninlike 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 section 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: Carabamazepin , Gabapentin, Lamotrigin, Phenitoein, 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 psycho therapy has an important role in AFP treatment. Myofacial 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

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Position

The assistant of oral medicine

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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