

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Therapeutic and analgesic efficacy of laser in conjunction with pharmaceutical therapy for trigeminal neuralgia

Protocol summary

Summary

Trigeminal neuralgia (TN) is the most common neuralgia in the head and neck region and a common cause of orofacial pain. It is routinely treated with carbamazepine. Laser, acupuncture are among other treatment modalities for this condition. This study sought to assess the efficacy of laser therapy in conjunction with carbamazepine for treatment of TN. Method: Qualified individuals were classified in two groups, with double blind randomization method, one patient and other analyzer. Inclusion criteria: Patients with definite diagnosis of TN according to the criteria of the International Headache Society (IHS) were included. Patients who were under standard pharmaceutical treatment for TN but had not experienced any improvement were also included. Exclusion criteria: pregnancy Patients. All patients received 100mg carbamazepine at baseline and another 100mg after two days for pain control. In the case group, low level laser therapy (LLLT) was also performed in addition to pharmaceutical therapy. Sham laser was used in the control group instead of LLLT. Treatment was continued for 10 sessions (3 days a week). The main consequence is a reduction in pain intensity and effectiveness of the laser.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601142464N15**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-23, 1395/10/03

Registrant information

Name

Shamsolmolok Najafi

Name of organization / entity

Faculty of Dentistry, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Dental Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic and analgesic efficacy of laser in conjunction with pharmaceutical therapy for trigeminal neuralgia

Public title

Therapeutic and analgesic efficacy of laser in conjunction with pharmaceutical therapy for trigeminal neuralgia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with definite diagnosis of TN according to the criteria of the International Headache

Society (IHS) were included [HIS 3 with ICD-10 (G44.0) coding]; Patients who were under standard pharmaceutical treatment for TN but had not experienced any improvement were also included. Exclusion criteria: pregnancy Patients

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**

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

The ethics committee of Tehran University of Medical Sciences / School of Dentistry, Tehran Universi

Street address

Shariati 3 Way Mahan, Khani Abad neo-Ave, Tehran, School of Dentistry, Tehran University of Medical Sciences International Campus, Tehran

City

Tehran

Postal code**Approval date**

2016-02-08, 1394/11/19

Ethics committee reference number

IR.TUMS.VCR.REC.1395.498

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

Trigeminal neuralgia

ICD-10 code

G50.0

ICD-10 code description

Syndrome of paroxysmal facial pain Tic douloureux

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

Compare the severity of pain

Timepoint

Before treatment - Upon completion of treatment- At two months after completion of treatment

Method of measurement

Visual Analog Scale

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

The side effects of the drug include dizziness

Timepoint

Before treatment- Upon completion of treatment-At two months after completion of treatment

Method of measurement

According patient

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

Intervention Group: Laser treatment with medication Medication: Tablets 200 mg orally, once a day for three months Laser: GaAIAS diode laser with a wavelength of 810 nm, continus form, dose 6.36 J/cm for over ten treatment sessions 3 times a week. Time laser irradiation for 25 seconds and a maximum power of 200 mW.

Category

Treatment - Drugs

2**Description**

Control group: Medication with sham laser Medication: Carbamazepine, tablets, 200 mg orally, once a day for three months Laser: Sham laser

Category

Treatment - Drugs

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

Tehran University of Medical Sciences / School of Dentistry, Tehran University of Medical Sciences I

Full name of responsible person**Street address**

Shariati 3 Way Mahan, Khani Abad neo-Ave, Tehran, School of Dentistry, Tehran University of Medical Sciences International Campus, Tehran

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr Abbas Akhondi

Street address

Ghods streets, Enghelab ave, Faculty of Dentistry, Dental Research Center, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dental Research Center, Tehran 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

Tehran University of Medical Sciences / School of Dentistry, Tehran University of Medical Sciences I

Full name of responsible person

Dr. Shamsoulmolouk Najafi

Position

Faculty and Assistant Professor

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