

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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 (LLL) was also performed in addition to pharmaceutical therapy. Sham laser was used in the control group instead of LLL. 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8833 0375

##### Email address

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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 University

**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, continuous 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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## Person responsible for scientific inquiries

### Contact

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**Position**

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## Person responsible for updating data

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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*