

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effect of non-ablative non-thermal co2 laser therapy(NANTL) on trigeminal neuralgia(double blind randomized clinical trial)

#### Protocol summary

##### Summary

Trigeminal neuralgia is a sudden pain radiating along the branch of the fifth nerve that usually appears unilaterally. It is the most painful part of many situations. A first step in pain control is drug therapy and carbamazepine is the standard drug for the treatment of pain. However, drug resistance during the treatment period, is leading to higher doses of medicine and surgery, which ultimately causes complications in both these cases. One of the new techniques for pain control is the use of laser therapy. The aim of our study is to offer better, safer treatment and faster reduce pain, with fewer side effects for patients with Trigeminal neuralgia (severe pain). In this randomized clinical trial (RCT) on 30 patients with trigeminal neuralgia that refer to neurology clinic of Imam Reza and the Oral medicine department of Shiraz university that will be treating with carbamazepin, are being conducted. Diagnosis of trigeminal neuralgia is confirmed by oral medicine specialist or neurologist. People with multiple sclerosis (MS) and has a history of herpes zoster (post herpetic neuralgia) are excluded. The general process for patients and their consent has been explained. Patients were randomly divided into two groups and control. VAS is taken from the patient before starting work. A gel layer contains a lot of water (no analgesic effect) on points for co2 laser is placed. Laser is emitted on the branches of the trigeminal nerve and TRIGGER point. for control group laser is off(sham). Immediately after laser therapy, one week, one month and three months later, VAS is taken from the patient. Patient and operator are using protective eyewear. This variable is the degree of pain reduction.

#### General information

##### Acronym

NANTL

##### IRCT registration information

IRCT registration number: **IRCT2013052113406N1**

Registration date: **2013-12-25, 1392/10/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-25, 1392/10/04

##### Registrant information

###### Name

Fahimeh Rezazadeh

###### Name of organization / entity

Dental school of shiraz university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1628 9917

###### Email address

rezazadehf@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-12-21, 1392/09/30

##### Expected recruitment end date

2014-05-19, 1393/02/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of effect of non-ablative non-thermal co2 laser therapy(NANTL) on trigeminal neuralgia(double blind randomized clinical trial)

## Public title

Evaluation of effect of non-ablative non-thermal laser therapy on trigeminal neuralgia

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criterion: trigeminal neuralgia that use carbamazepin for treatment. Exclusion criteria: MS and postherpetic neuralgia.

## 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

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences Ethics Committee

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

##### Postal code

#### Approval date

2013-12-02, 1392/09/11

#### Ethics committee reference number

CT-P-92-5731

## Health conditions studied

### 1

#### Description of health condition studied

Trigeminal neuralgia

#### ICD-10 code

G50.0

#### ICD-10 code description

Trigeminal neuralgia

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Immediately after treatment, 2 weeks after and 1, 2, 6 months after

#### Method of measurement

VAS

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

treatment with laser in intervention group

#### Category

Treatment - Other

### 2

#### Description

sham laser in control group

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Oral Medicine Department

##### Full name of responsible person

##### Street address

Shiraz University of Medical Sciences

##### 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. Gholamreza Hatam

**Street address**

Shiraz University of Medical Sciences

**City**

Sshiraz

**Grant name****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 University of Medical Sciences

**Full name of responsible person**

Fatemeh Mosalanegad

**Position**

Student(under graduated)

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Shiraz University of Medical Sciences

**Full name of responsible person**

Fahimeh Rezazadeh

**Position**

Assistant professor

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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*