

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

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Iran (Islamic Republic of)

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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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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*