Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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). Immediatlly 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)
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Scienses

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
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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