

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect Of LLLT(low level laser therapy) On Idiopathic Trigeminal Neuralgia Pain

Protocol summary

Study aim

Determining the effect of low power laser therapy on pain in patients with trigeminal neuralgia.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 24 patients.

Settings and conduct

In this double-blind study, patients with a definitive diagnosis of idiopathic trigeminal neuralgia will be selected from a neurologist's clinic and will be included in the study. Pain score will be measured with VAS. Pain is measured before and after laser therapy (after each week of laser therapy and one month after the end of treatment). Laser treatment is performed in 9 sessions, three days a week. The laser used in this research will be use with a wavelength of 940 nm with a density of 10 joules in continuous state. Radiation in laser therapy will be performed at the onset points of pain and in the absence of pain onset points, 2 to 3 points in the pain path will be selectively radiated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients whose definitive diagnosis of trigeminal neuralgia is based on IHS (International Headache Society) criteria. 2. People who are seeing a doctor for the first time for treatment or have received standard medication but have had no effect on their recovery. 3. Idiopathic disease (such as malformation of blood vessels, brain tumors, or diseases such as multiple sclerosis that cause the disease). Exclusion criteria: 1. Pregnancy 2. There is a blood problem 3. Existence of liver dysfunction 4. Dissatisfaction of the person to participate in the study

Intervention groups

low level laser therapy

Main outcome variables

pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049655N1**

Registration date: **2021-02-22, 1399/12/04**

Registration timing: **prospective**

Last update: **2021-02-22, 1399/12/04**

Update count: **0**

Registration date

2021-02-22, 1399/12/04

Registrant information

Name

Abbas Davodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3485 0353

Email address

abbasdavodi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-04-30, 1400/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Public title

The effect of low-level laser therapy on spontaneous nerve pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients whose definitive diagnosis of trigeminal neuralgia is based on the IHS (International Headache Society) People who are seeing a doctor for the first time for treatment or have received standard medication but have had no effect on their recovery. Idiopathic disease (such as vascular malformations, brain tumors, or diseases such as multiple sclerosis that cause the disease).

Exclusion criteria:

Pregnancy Blood problem liver functional problem Dissatisfaction to contribute in the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are randomly divided into intervention and control groups. For this purpose, AABB, ABAB, BBAA, BABA, ABBA and BAAB quadruple blocks are used to balance the allocation to each group. It is also a method of selecting a random block using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study. Due to the fact that laser treatment is performed for one group and silent laser is applied for the other group, patients are unaware of which group they are in. The researcher who meets the VAS criteria for the patient is also unaware of what group he or she belongs to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht Place

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.ARAKMU.REC.1399.160

Health conditions studied

1

Description of health condition studied

Neuralgia

ICD-10 code

G50.0

ICD-10 code description

Trigeminal neuralgia

Primary outcomes

1

Description

Pain score

Timepoint

pain score at the beginning of the study (before the intervention) and immediately after each session of laser therapy and one month after the intervention

Method of measurement

VISUAL ANALOG SCALE

Secondary outcomes

1

Description

Duration of pain relief

Timepoint

At the end of study

Method of measurement

checklist

Intervention groups

1

Description

Intervention group: Treatment will start with 100 mg of carbamazepine and add 100 mg to the dose once every three days (depending on the patient's pain intensity). This process continues until the pain relief (increase to the maximum allowable dose). laser therapy is performed by rays with a wavelength of 940 nm with a density energy of 10 joules per square centimeter continuously (Biolase Technology, 940 diode, CA, USA). Laser treatment is performed in 9 sessions three days a week. Laser therapy is performed at the onset of pain. Based on previous studies, in this study, the effect of laser therapy and carbamazepine on pain in the experimental group is measured simultaneously.

Category

Treatment - Devices

2

Description

Control group: Treatment will start with 100 mg of carbamazepine and add 100 mg to the dose once every three days (depending on the patient's pain intensity). This process continues until the pain relief (increase to the maximum allowable dose). In addition, an unreal laser is used for the control group in which the laser is on but there is no radiation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurologist Clinic

Full name of responsible person

Abbas Davodi

Street address

Hafez4 Street, Ashtiani Boulevard, Pardis1 Alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Abbas Davodi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Latest degree

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Fax**Email**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all of data

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

no analysis are allowed

From where data/document is obtainable

registrar email

What processes are involved for a request to access data/document

contact with registrar

Comments