Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 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)

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+98 86 3485 0353

Email address
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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

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

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

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Hafez4 Street, Ashtiani Boulevard, Pardis1 Alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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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