

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the Effect of Low-level Laser Therapy on the Neurosensory Disturbances Following Inferior Alveolar Nerve Lateralization Surgery: A Randomized Clinical Trial

Protocol summary

Study aim

The aim of this study is to evaluate the effect of low-power laser on neurosensory disturbance following inferior alveolar nerve lateralization surgery.

Design

A randomized controlled clinical trial with parallel double blind randomised groups

Settings and conduct

Patients undergoing bilateral inferior alveolar nerve lateralization surgery in private office are randomly divided into two groups for each patient one side will be irradiated by low level laser and the other side will take placebo laser. Neurosensory examinations are performed once before surgery for the criterion and three times after surgery at one month, three months and six months. The exams are repeated and compared to the opposite side that did not receive the laser.

Participants/Inclusion and exclusion criteria

Patients Applicant for Dental Implant Therapy on Both Posterior Mandible with Insufficient Bone Height who are candidates for inferior alveolar nerve lateralization surgery. Without the following conditions: History of facial fractures, History of long term headache, Psychological disorders, Neurologic disorders, Diabetes, History of taking anti epileptic drugs, Clear nerve damage during surgery, Pregnancy.

Intervention groups

The intervention in this study is the use of low-power laser on one side of patients undergoing bilateral lower alveolar nerve lateralization. The other side will be the control group and will receive the low-power laser placebo.

Main outcome variables

The five specific tests for neurosensory evaluation are the main outcome variables that are: Visual analogue scale; Pain discrimination test; Two point discrimination test; Directional discrimination test; Cold discrimination

test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200123046230N1**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Arash Azaripour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6638 4856

Email address

arashazaripour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Low-level Laser Therapy on the Neurosensory Disturbances Following Inferior Alveolar Nerve Lateralization Surgery: A Randomized Clinical Trial

Public title

Evaluation of the Effect of Low-level Laser Therapy on the Neurosensory Disturbances Following Inferior Alveolar Nerve Lateralization Surgery: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients Applicant for Dental Implant Therapy on Both Posterior Mandible with Insufficient Bone Height who candidates for inferior alveolar nerve lateralization surgery

Exclusion criteria:

History of facial fractures History of long term headache Psychological disorders Neurologic disorders Diabetes History of taking anti epileptic drugs Clear nerve damage during surgery Pregnancy

Age

From 20 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 20

More than 1 sample in each individual

Number of samples in each individual: 2

Each participant is assigned two sample one mandibular side takes laser and the other side does not take

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization is performed with the coin toss for each participant and receives one side based on the laser coin toss

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining consent from patients, randomly assigned to the case group (low power laser) and control group (no laser irradiation) for each patient The device is switched off and the patient assumes that both sides are laser treated The researcher is also unaware of the laser being irradiated and the laser treatment process is performed by the technician

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran Azad University of Medical Sciences - Faculty of Dentistry

Street address

No. 112 , Hodhod 1 building , North navab highway

City

Tehran

Province

Tehran

Postal code

1319813719

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.024

Health conditions studied**1****Description of health condition studied**

Inferior alveolar nerve neurosensory disturbance

ICD-10 code

G50.8

ICD-10 code description

Other disorders of trigeminal nerve

Primary outcomes**1****Description**

Sensory function of the inferior alveolar nerve

Timepoint

Before surgery and 1, 3 and 6 months after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Surgery will be performed by one of the experienced professors with the same standard protocol and materials. After surgery, the intervention

group was treated with laser therapy with a 0.3 watt diode laser and 6 joule power (InGaAlP; wavelength 660nm; Thor DD2 Control Unit, Thor, London, UK) for 8 sessions at 72 intervals. It will be placed in the oral alveolar nerve pathway orally for 20 seconds per square centimeter per session.

Category

Treatment - Devices

2**Description**

Control group: Surgery will be performed by one of the experienced professors with the same standard protocol and materials. After surgery, the control group is exposed to placebo laser irradiation with a 0.3 watt laser diode and 6 joules of power (InGaAlP; wavelength 660nm; Thor DD2 Control Unit, Thor, London, UK) In 8 sessions at 72 hours intervals for 20 seconds per square centimeter, the inferior alveolar nerve pathway will be inhaled orally but the device will be switched off and the laser will not be illuminated

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Buali hospital of tehran

Full name of responsible person

Arash Azaripour Esfahani

Street address

Damavand Street

City

Tehran

Province

Tehran

Postal code

17117

Phone

+98 21 3334 8036

Fax**Email**

booali.hospital96@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Faculty of Dentistry, Islamic Azad University of Medical Sciences

Full name of responsible person

Arash Azizi

Street address

Ninth Neyestan , Pasdaran Street

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

arashazizi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Faculty of Dentistry, Islamic Azad University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Private

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**

Faculty of Dentistry, Islamic Azad University of Medical Sciences

Full name of responsible person

Arash Azaripour Esfahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

No. 112 , Hodhod building 1 , North Navab Highway

City

Tehran

Province

Tehran

Postal code

1319813719

Phone

+98 21 6638 4856

Email

arashazaripour@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Faculty of Dentistry, Islamic Azad University of Medical Sciences

Full name of responsible person

Arash azaripour Esfahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Email

arashazaripour@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Faculty of Dentistry, Islamic Azad University of
Medical Sciences

Full name of responsible person

Arash Azaripour Esfahani

Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

Main outcome information

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Shoal scholars in academic institutions

Under which criteria data/document could be used

With the written permission of the researcher

From where data/document is obtainable

By mail to researcher: arashazaripour@gmail.com

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

At least 6 months after contacting the researcher

Comments