

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of the adjunctive effect of photobiomodulation therapy with Nd: YAG laser(1064nm) on decrease of lower lip paresthesia and dysesthesia in patients with inferior alveolar nerve damage

#### Protocol summary

##### Study aim

Determining and comparing the auxiliary effect of using low level Nd:YAG laser on reducing lower lip paresthesia and dysesthesia in case and control groups and also based on the referrals from the time of the accident

##### Design

A controlled, parallel-group, double-blind, randomized clinical trial on 50 patients. A table of random numbers will be used for randomization.

##### Settings and conduct

In this research, the study subjects will be selected based on the inclusion criteria among the patients referred to Tabriz Dental Faculty who have lower lip paresthesia or dysesthesia problem. After determining the samples, obtaining written consent and explaining the method and purpose of the study, the demographic information form is completed for each patient separately. Participants in both groups are subjected to low level laser therapy by Nd:YAG laser for 10 sessions. In the case group, laser therapy will be performed in a real way, and in the control group, the off laser will be used with a completely similar method. Blinding will be done for the participants, the researcher and the outcome assessor and the data analyst.

##### Participants/Inclusion and exclusion criteria

Paresthesia and dysesthesia of the lower lip, which are classified as 1, 2, and 3 in the Sunderland classification, lack of previous intervention related to nerve damage

##### Intervention groups

First, the patients are divided into two groups, over 6 months and under 6 months, based on the duration of the injury, and then they are randomly divided into case and control groups. In the case group, patients receive routine treatment plus low level laser therapy, and in the control group, patients receive routine treatment plus placebo.

##### Main outcome variables

The main outcomes of the study include visual analogue scale (VAS) index and two-point discrimination test.

#### General information

##### Reason for update

##### Acronym

LLLT

##### IRCT registration information

IRCT registration number: **IRCT20221218056853N1**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

##### Registration date

2022-12-26, 1401/10/05

##### Registrant information

##### Name

Meghdad Eslami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3660 9691

##### Email address

meghdadeslami72@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-06-21, 1402/03/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the adjunctive effect of photobiomodulation therapy with Nd: YAG laser(1064nm) on decrease of lower lip paresthesia and dysesthesia in patients with inferior alveolar nerve damage

**Public title**

Laser therapy in lower lip paresthesia and dysesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Paresthesia and dysesthesia of the lower lip, which are classified as 1, 2, and 3 in the Sunderland classification  
Not performing previous intervention related to nerve damage

**Exclusion criteria:**

The presence of mass in the face, jaw and neck area  
Active infection in the chin and jaw area  
Involvement of other branches of the trigeminal nerve except the inferior alveolar nerve

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: 50

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method is simple and its unit is individual. The randomization tool will be a table of random numbers. Based on this, the type of intervention will be marked with code A (real laser therapy) and code B (placebo) and will be placed inside sealed envelopes. Then the envelopes will be placed in a bag and mixed. The envelopes will be randomly taken out of the bag and will be presented to the relevant intervention patients by observing the intervention code. None of the patients will be informed about the intervention of another patient.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, it will be explained to the patients that there is a possibility of their placement in the real or fake laser therapy group, but the patients will not know their group and the laser device will be used in both groups. Patients wear blindfolds during laser therapy to protect them from laser radiation and do not notice the real or

fake laser therapy. Laser therapy is performed by a person who has no knowledge of real or fake laser therapy (only the aiming beam is turned on) and evaluates the results of the study in each session. Data analysis will also be done by a person who does not know about the groups

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Approval date**

2022-12-04, 1401/09/13

**Ethics committee reference number**

IR.TBZMED.REC.1401.839

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

Lower lip paresthesia and/or dysesthesia

**ICD-10 code**

R20.2

**ICD-10 code description**

Paresthesia of skin

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

visual analogue scale (VAS)

**Timepoint**

Before starting the intervention and in every 10 laser therapy sessions

**Method of measurement**

In this way, Scale = 0 is considered for lack of sensitivity and Scale = 10 is considered as normal sensitivity and the patient is asked to choose a number between 0 and

2**Description**

two-point discrimination test

**Timepoint**

Before starting the intervention and in every 10 laser therapy sessions

**Method of measurement**

Static two-point discrimination test is performed by two objects on the skin, which can be used to measure the distance between two points. These objects should be blunt and non-sharp and have the ability to stimulate pain receptors. The closest distance that the patient can distinguish two points from one point is recorded

**Secondary outcomes**

empty

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

First Intervention group: Patients with paresthesia and dysesthesia of the lower lip with less than 6 months of injury who receive routine treatment plus low level laser therapy.

**Category**

Treatment - Other

2**Description**

First Control group: Patients with paresthesia and dysesthesia of the lower lip less than 6 months after the injury, who receive routine treatment plus placebo.

**Category**

Treatment - Other

3**Description**

Second Intervention group: Patients with paresthesia and dysesthesia of the lower lip with more than 6 months of injury who receive routine treatment plus low level laser therapy.

**Category**

Treatment - Other

4**Description**

Second Control group: Patients with paresthesia and dysesthesia of the lower lip more than 6 months after the injury, who receive routine treatment plus placebo.

**Category**

Treatment - Other

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

Tabriz dental faculty

**Full name of responsible person**

Meghdad Eslami

**Street address**

Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3335 5921

**Email**

info@dentistryfac.tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Sudabeh Kimiayi

**Street address**

Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3334 0310

**Email**

info@dentistryfac.tbzmed.ac.ir

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Meghdad Eslami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No.346, 2th Golestan Ave, Ostandari Blvd

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5158943846

**Phone**

+98 41 3660 9691

**Fax****Email**

meghdadeslami72@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Meghdad Eslami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No.346, 2th Golestan Ave, Ostandari Blvd

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5158943846

**Phone**

+98 41 3660 9691

**Fax****Email**

meghdadeslami72@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Meghdad Eslami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No.346, 2th Golestan Ave, Ostandari Blvd

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5158943846

**Phone**

+98 41 3660 9691

**Fax****Email**

meghdadeslami72@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**

The access period starts from 2023

**To whom data/document is available**

All people can apply for study documents.

**Under which criteria data/document could be used**

The data of this study can be used to investigate the effect of low level laser therapy in patients who only have paresthesia or dysesthesia of the lower lip.

**From where data/document is obtainable**

Meghdad Eslami 0098 9148528993

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

After submitting the application, the study documentation file will be sent as soon as possible

**Comments**