

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The comparison of 940nm and 810nm diode laser type effects on the repair of inferior alveolar sensory nerve damage

#### Protocol summary

##### Study aim

Determination of the effect of two types of 940nm and 810nm diode lasers on repair of infra-aleuolular sensory nerve injury in patients referred to Laser Research Center of the Faculty of Dentistry, University of Tehran during the year 1397-98.

##### Design

Clinical trials with control group, with parallel groups, blind, randomized

##### Settings and conduct

The first and second groups underwent irradiation of the infra-alluvial nerve pathway in three regions, including nerve insertion into the mandibular position of Foramen, Lip and one region in the two regions. The treatment will continue for 12 sessions (3 days a week). In each session, laser radiation with a power of 400mW in 20 seconds for each area is done. The area of each area under the radiation is 1 cm<sup>2</sup> and the radiation dose per session is 8 J / cm<sup>2</sup>.

##### Participants/Inclusion and exclusion criteria

Less than six months have suffered a nerve damage due to dental treatment and have not undergone any treatment.

##### Intervention groups

Patients are divided into three groups: 1) under 810nm laser irradiation, 940nm laser irradiation, and 3) non-radiation laser (control group).

##### Main outcome variables

Four objective tests and a subjective test will be used to evaluate nerve repair. For all individuals, a full-scale clinical neurosensory test (CNT), including A (Brush stroke and 2-point discrimination), Bpr (pinprick nociception and thermal discrimination), will be performed. The intensity of fidelity and satisfaction is assessed using the Numerical Scale (0 is not at all satisfied - 10 is fully satisfied) and CNT will be evaluated before and after the treatment (after the first, third, seventh, and twelfth days).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190520043644N1**

Registration date: **2019-12-15, 1398/09/24**

Registration timing: **retrospective**

Last update: **2019-12-15, 1398/09/24**

Update count: **0**

##### Registration date

2019-12-15, 1398/09/24

##### Registrant information

##### Name

Hooman Ebrahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8867 3895

##### Email address

hooman.ebrahimi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-27, 1398/03/06

##### Expected recruitment end date

2019-08-28, 1398/06/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of 940nm and 810nm diode laser type effects on the repair of inferior alveolar sensory nerve damage

#### Public title

Effect of laser diode on the repair of inferior alveolar sensory nerve damage

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

With sensory and neuropathic disturbances Sensory nerve damage due to dental treatments Less than 6 months of injury Treated with laser Systemic diseases

##### Exclusion criteria:

Sensory nerve damage is due to trauma Already exposed to laser radiation History of drug addiction Smoking

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

#### Sample size

Target sample size: **39**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The randomization method consists of a quadrilateral random block In this method the size of the blocks is selected at random Each block contains an equal number of each group For ethical consideration and standard treatment, all patients were treated with vitamin B1 300 mg once daily and gabapentin 100 mg once daily Then patients are divided into three groups: 810nm diode laser, 940nm diode laser irradiation and no laser irradiation (control group)

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The patient does not know what diode (940nm laser diode or 810nm laser diode or normal diode) will light up his nerve. Clinical supervision of the device and only diode light to the patient's nerve and is not known about the type of diode used. The outcome evaluator will only review the patient and record the result in a file that does not use the type of diode he or she uses.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Department of Dentistry, Islamic Azad University, Tehran, Iran

##### Street address

No. 9, Neyestan 9 Ave., Pasdaran Plvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1946853314

#### Approval date

2019-05-04, 1398/02/14

#### Ethics committee reference number

IR.IAU.DENTAL.REC .1398.008

## Health conditions studied

### 1

#### Description of health condition studied

Inferior alveolar sensory nerve damage

#### ICD-10 code

T88.5

#### ICD-10 code description

Other complications of anesthesia

## Primary outcomes

### 1

#### Description

The number of people with a fatigue rating above 3

#### Timepoint

After the sessions 1, 3, 7 and 12 treatment

#### Method of measurement

Numerical Scale

### 2

#### Description

The number of people who tested the clinical neurosensory test

#### Timepoint

After the sessions 1, 3, 7 and 12 treatment

#### Method of measurement

Brush Stroke test with the criterion for detecting one of two horizontal and vertical movements, Two Point Discrimination test with a minimum recording distance of less than 10 mm, Thermal Discrimination test with a heat and cold detection criterion, and a Pin Prick Nociception test with a metric for registering more hits. From 30%

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Under the 810 nm diode laser beam 810nm Laser: Diode laser with GaAlAs medium (Gallium Aluminum Arsenide) with 810nm wavelength manufactured by Thor UK Different Sessions: The first three days of the seventh to the twelfth hour Treatment Specifications: At each session, 400mW laser irradiation in twenty seconds for the three nerve entry sites to the mandibular foramen, lip, and one area between these two regions is equal to 1cm<sup>2</sup> of Spot Area

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Under the 940nm diode laser beam 940nm Laser: 940nm Medium GaInP (Gallium Endium Phosphate) Diode Laser Made by US Biolase Different Sessions: The first three days of the seventh to the twelfth hour Treatment Specifications: At each session, 400mW laser irradiation in twenty seconds for the three nerve entry sites to the mandibular foramen, lip, and one area between these two regions is equal to 1cm<sup>2</sup> of Spot Area

#### Category

Treatment - Other

### 3

#### Description

Control group: No intervention For ethical consideration and standard treatment, all patients were treated with vitamin B1 300 mg once daily and gabapentin 100 mg once daily

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Laser Research Center, Faculty of Dentistry, University of Tehran

##### Full name of responsible person

Hooman Ebrahimi

##### Street address

End of Worker North - Next to Hakim Highway - Tehran Dental School-

##### City

Tehran

##### Province

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۱۳۳۹۹۵۵۹۹۱

##### Phone

+98 21 8801 5950

##### Email

dentistry@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Arash azizi

##### Street address

No. 9, Neyestan 9 Ave., Pasdaran Plvd.

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##### Phone

+98 21 2256 4571

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hooman.ebrahimi@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Islamic Azad University

##### 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

Islamic Azad University

##### Full name of responsible person

Hooman Ebrahimi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University  
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Masoumeh Kargar  
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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

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available