

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of photobiomodulation on neurosensory recovery of patients with neurotmesis of inferior alveolar nerve due to mandibular traumatic fracture

Protocol summary

Study aim

The effect of photobiomodulation on neurosensory recovery of patients with neurotmesis of the inferior alveolar nerve due to mandibular traumatic fracture

Design

A concealed, randomized, triple-blinded clinical trial with 52 patients enrolled between June and July 2020, and followed for one year

Settings and conduct

The clinical trial will be conducted at the Army Dental School and will be triple blinded (including Patients, outcome assessor, and analyzer). Fifty-two patients will be randomly divided into two groups of 26 using Randomizer software (Version 4.0) and 12 sessions of laser therapy will be performed for the intervention group and a laser probe will be placed on the area of the control group turned off.

Participants/Inclusion and exclusion criteria

Patients with a history of complete inferior alveolar nerve severance due to a mandibular fracture who have received standard open reduction and internal fixation and the neurosensory disorder persists for at least 6 months

Intervention groups

For the intervention group, 12 sessions of laser therapy on the area with neurosensory disturbances with diode laser will be performed, while for the control group, the laser probe will be placed on the area turned off.

Main outcome variables

Light Touch Sensation test, 2-Point Discrimination test, Thermal Test, Electric pulp test, Oral Health Impact Profile Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190505043481N1**

Registration date: **2021-09-20, 1400/06/29**

Registration timing: **retrospective**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Nariman Nikparto

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

2020-03-10, 1398/12/20

Actual recruitment end date

2020-05-20, 1399/02/31

Trial completion date

2021-05-21, 1400/02/31

Scientific title

The effect of photobiomodulation on neurosensory recovery of patients with neurotmesis of inferior alveolar

nerve due to mandibular traumatic fracture

Public title

The effect of laser therapy on lip and chin sensation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a history of displaced fractures of the mandibular body, angle, or ramus Displacement of fracture segments in panoramic radiograph should delineate complete nerve severance (Sunderland 5) Patients who have received ideal treatment of open reduction and internal fixation At least six months have elapsed since open reduction and internal fixation treatment, and the neurosensory disorder persists. All patients should be systemically healthy.

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Computer software: Randomizer (Version 4.0)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients, outcome assessor, and analyzer will be blind. Laser therapy will be performed for the intervention group while the laser probe will be placed on the area of the control group turned off. Due to the invisibility of the laser beam and the silence of the probe when turned on, patients will not notice whether the device is turned on or off. The outcome assessor will also evaluate patients in a separate room and will be blind to the patient group. The analyzer will also be blind to the group of patients because the names of the groups will not be in the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

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AJA University of Medical Sciences, Etemadzadeh St. , West Fatemi st. , Tehran, Iran

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Province

Tehran

Postal code

1411718541

Approval date

2020-05-27, 1399/03/07

Ethics committee reference number

IR.AJAUMS.REC.1399.044

Health conditions studied

1

Description of health condition studied

chin and lip anesthesia due to mandibular trauma

ICD-10 code

R20.2

ICD-10 code description

Dysesthesia

Primary outcomes

1

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Light touch sensation test with cotton swap

2

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Two-Point discrimination test

3

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Thermal test

4

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Electric pulp test

5

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Oral health impact profile questionnaire

6

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Light touch sensation test with wooden cotton swap

7

Description

Improvement in neurosensory function of inferior alveolar nerve

Timepoint

Baseline, after all 12 sessions and 3,6,9,12 months after last session

Method of measurement

Light touch sensation test with dental needle

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who receive laser therapy on the area with neurosensory impairment in 12 sessions with Gallium Aluminum Arsenide diode laser. Control group: Patients who do not receive any intervention and the laser probe will be placed on the area with

neurosensory impairment turned off for 12 sessions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

AJA University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

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

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Nariman Nikparto

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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

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Position

Assistant professor

Latest degree

Specialist

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

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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 collected deidentified IPD

When the data will become available and for how long

starting after publication for 6 months

To whom data/document is available

for people working in academic institutions

Under which criteria data/document could be used

there are no specific criteria

From where data/document is obtainable

With an email to corresponding author

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

The accepted proposal from an official committee should be provided and only if our data was relevant to the

proposal needs, the data will be sent
Comments