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

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Iran (Islamic Republic of)

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+98 21 8888 7409

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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
Street address
AJA University of Medical Sciences, Etemadzadeh St. , West Fatemi st. , Tehran, Iran
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Tehran
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 in12 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

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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
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Person responsible for updating data

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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