Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of low – level laser irradiation on healing process of lower lip hypoesthesia following sagittal split ramus osteotomy

Protocol summary

Study aim
Evaluate the influences of low-level laser therapy on improvement of lower lip neurosensory disturbance following sagittal split ramus osteotomy.

Design
Controlled clinical trial with parallel groups, double blinded, individual simple random sampling

Settings and conduct
40 patients will require lower jaw orthognathic surgery referring to the maxillofacial surgery ward, Taleghani hospital, Tehran are included in the study.The patients will be selected in an individual simple random sampling. Diode laser irradiation will be performed in intervention group patients following lower jaw sagittal osteotomy surgery. The examiner and the patients are blinded to the groups. After that the sensory signs of the patients will be assessed in 3, 6, and 12 months periods.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who undergo sagittal split osteotomy surgery, Nerve damage is as neuropraxia, No technical error is occurred during surgery, No previous nerve damage is mentioned, No previous facial surgery is mentioned, Patients are not medically compromised, Patients do not consume anticonvulsants and antidepressants drugs. Exclusion criteria: History of neurosensory disturbance in the facial area, Inappropriate surgical technique, Neurotmesis or axonotmesis happening, Uncooperative patients

Intervention groups
Intervention group patients will undergone laser therapy by GaAlAs diode laser. Laser irradiation would be performed 6, 24, 48, and 72 hours following surgery and every other day for the next two weeks (10 sessions). Diode laser wavelength is 810 nm, the power density is 8.4 j/cm2, power is 70 mW, and the beam diameter is 8mm. Control group: The probe is moved on the patients' faces whilst the laser unit is off.

Main outcome variables
Patient's satisfaction, recovery of facial skin sensation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180930041179N1**
Registration date: **2018-12-21, 1397/09/30**
Registration timing: **retrospective**

Last update: **2018-12-21, 1397/09/30**
Update count: **0**

Registration date
2018-12-21, 1397/09/30

Registrant information

Name
Mohammad Esmaeelinejad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-12, 1396/07/20

Expected recruitment end date
2018-03-11, 1396/12/20

Actual recruitment start date
2017-10-12, 1396/07/20

Actual recruitment end date
2018-03-11, 1396/12/20

Trial completion date
2018-09-06, 1397/06/15

Scientific title

Effect of low – level laser irradiation on healing process of lower lip hypoesthesia following sagittal split ramus osteotomy

Public title
Effect of low level laser on nerve healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who undergo sagittal split osteotomy surgery. Nerve damage is as neuropraxia. No technical error is occurred during surgery. No previous facial surgery is mentioned. No previous nerve damage is mentioned. Patients are not medically compromised. Patients do not consume anticonvulsants and antidepressants drugs.
Exclusion criteria:
History of previous orthognathic surgery History of neurosensory disturbance in the facial area Inappropriate surgical technique or complication occurrence Neurotmesis or axonotmesis happening Medically compromised patients Uncooperative patients
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be divided into the groups in an individual simple random sampling (SRS) manner. In this order random number table will be used. Any of 500 referred patients to the hospital who need orthognathic surgery will have a number. These numbers will be put in the number table without any pattern and totally disorderly. The numbers are found by a second blinded person in order to allocation concealment. At first a point is selected to start. By default, the direction from left to right is set. By moving on the table each number will be recorded which is the person who is included in the study. By default, numbers under 250 are included in the intervention group and numbers over 250 are included in control group. This process will be continued until 40 patients (sample size) are completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Every patient is included in control or intervention group randomly and is not informed about that.In control group the probe is used whilst the laser unit is off. In this order the patients will not understand that whether the laser is irradiated or not and are blinded to the survey. The examiner who assesses the outcomes is not aware that each patient is whether in the intervention group or not. Actually the study is designed to be double blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiatallah University of Medical Sciences
Street address
Vice chancellor for research, Baqiyatallah university, Sheikhbahaei Ave., Molasadra Ave., Vanak square
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2016-10-03, 1395/07/12
Ethics committee reference number
IR.BMSU.REC.1395.082

Health conditions studied

1

Description of health condition studied
Neurosensory disturbance in facial area
ICD-10 code
G50.8
ICD-10 code description
Other disorders of trigeminal nerve

Primary outcomes

1

Description
Patient’s satisfaction
Timepoint
One, three, six, and twelve months after laser therapy
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description

Pinprick test

Timepoint

One, three, six, and twelve months after laser therapy

Method of measurement

Pinprick test; is defined as the patient's ability to identify the sharp needle touching the affected skin. Dental probe is used for this test with the constant force.

2

Description

Thermal test

Timepoint

One, three, six, and twelve months after laser therapy

Method of measurement

Thermal test; which is defined as the patient's ability to discern either the heat or cool probe. Small glass tubes containing water at15°C and 50°C are used. The perception of either cold or hot stimulus is recorded.

3

Description

Two-point discrimination

Timepoint

One, three, six, and twelve months after laser therapy

Method of measurement

Two-point discrimination test; which is defined as the patient's ability to detect the two nearby objects contacting the face skin truly two distinct points, not one. A calibrated drawing compass was used with minimum error (reproducibility more than 95%).

Intervention groups

1

Description

Intervention group: Laser irradiation would be performed immediately, 24 hours, 48 hours, and 72 hours following surgery. Laser therapy is continued three times a week in the next two weeks (total 10 sessions). Diode laser wavelength is 810 nm, the power density is 8.4 j/cm2, power is 70 mW, and the beam diameter is 8mm.

Category

Treatment - Devices

2

Description

Control group: Laser irradiation would be performed immediately, 24 hours, 48 hours, and 72 hours following surgery. Laser therapy is continued three times a week in the next two weeks (total 10 sessions).probe is used whilst the laser unit is off

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Afshin Mohammad Alizadeh

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Arabi street, Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr.Mohsen Saberi

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Grant name

Grant code / Reference number

91001082

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

Yes

Title of funding source

Bagheiat-allah 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
Semnan University of Medical Sciences

Full name of responsible person
Mohammad Esmaeelinejad

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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