

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the effect of photobiomodulation therapy with 810 nm Diode laser on the recovery of mid face sensation following maxillary Lefort 1 surgery: A triple-blind, split-face, randomized controlled trial

Protocol summary

Study aim

determine the effect of photobiomodulation therapy with 810 nm Diode laser on the recovery of mid face sensation following maxillary Lefort 1 surgery

Design

The clinical trial will be performed as a split face, three-way blind, randomized, phase 3, on 10 patients. Excel random function was used for randomization.

Settings and conduct

This blind 3-sided clinical trial (patient, examiner and statistical analyst) is performed as a split face on patients aged 18 to 40 years who have referred to Shariati and Sina hospitals of Tehran University of Medical Sciences for Lefort 1 osteotomy. On the intervention side, laser therapy will be performed on days 1, 3, 7, 14, 21 and 28 after the operation. The laser probe on the control side is inactive at similar points and the patient will not know if the laser probe is on or off. All patients will be evaluated for neuroscience with standard sensory tests before and after surgery, as well as on days 1, 3, 7, 14, 21, 28, and 35 in the middle of the face on both sides of the control and intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No previous maxillofacial trauma , Absence of oral diseases, No uncontrolled systemic diseases Exclusion criteria: Existence or history of trauma or head and neck malignancies, Pregnancy and lactation, experiencing fractures or obvious nerve damage during surgery, Postoperative infection, Contraindication laser therapy

Intervention groups

In the middle part of the participants' face, one side is considered as the intervention area and the other side is considered as the control. Intervention: Laser therapy on days 1, 3, 7, 14, 21 and 28 after surgery Control: Lack of laser therapy

Main outcome variables

2point discrimination test thermal discrimination test
sharp blunt discrimination test brush stroke directional
test Patient satisfaction level using visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211127053194N1**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **prospective**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

Fatemeh Ostad khalil

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8834 0435

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of photobiomodulation therapy with 810 nm Diode laser on the recovery of mid face sensation following maxillary Lefort 1 surgery: A triple-blind, split-face, randomized controlled trial

Public title

The effect of laser therapy on recovery of facial sensation after upper jaw surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

No previous maxillofacial trauma
Absence of oral diseases
No uncontrolled systemic diseases
Age between 18 and 40 years

Exclusion criteria:

Existence or history of trauma or head and neck malignancies
Pregnancy and lactation experiencing fractures or obvious nerve damage during surgery
Postoperative infection
Contraindication laser therapy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Midface (from inferior orbital rim to the upper lip) on the left site, Midface (from inferior orbital rim to the upper lip) on the right site

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, using a simple randomization method with a table of random numbers, the intervention is assigned to one of the two right or left. In this way, in the table of random numbers from top to bottom, in case of collision with odd number, the intervention will be assigned to the right, and in case of collision with even number, the intervention will be assigned to the left. Move in the columns of the random number table from top to bottom until the number of samples is exhausted.

Blinding (investigator's opinion)

Triple blinded

Blinding description

During laser treatment, the patient will not feel any heat changes or pain during the laser treatment. The device probe is used on the control side with the same time as

intended on the intervention side in off mode. The patient (according to the above points) will be blind to which side of the mouth he receives the laser from. The person who measures the results of the study will be blind to this allocation. Also, labels A and B are considered for both intervention and control so that the statistical analyst is blind to the end of the data analysis relative to the allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences- faculty of dentistry

Street address

Faculty of dentistry (TUMS), ST north Kargar,

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.142

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

neurosensory disorder after Lefort 1 surgery

ICD-10 code

R20.2

ICD-10 code description

Disturbance of skin sensation

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

score of 2 point discrimination test

Timepoint

day preoperative and then on days 1, 3, 7, 14, 21, 28 and 35 postoperative

Method of measurement

The points of calipers are held against the skin at different distances from each other. The test determines

the minimal distance at which the patient can distinguish whether one or two points are in contact with the skin. This distance starts at 10 mm in the upper lip and 20 mm in the nasolabial fold, and gradually decreases by one millimeter each time the test is performed, until patient feel the 2 points as one point. The amount of distance that the patient first senses two points as one point is considered as an outcome. We will do this process 3 times and consider its average.

2

Description

score of brush directional stroke test

Timepoint

Day preoperative and then on days 1, 3, 7, 14, 21, 28 and 35 postoperative

Method of measurement

brush directional stroke test consisted of performing ten horizontal or vertical movements with a micro brush tip on the marked points (about 1 cm) and ask for the patient to report the direction. The number of correct answers is recorded from the number of 10 tests performed.

3

Description

score of thermal discrimination test

Timepoint

Day preoperative and then on days 1, 3, 7, 14, 21, 28 and 35 postoperative

Method of measurement

In this test, small glass tubes filled with cold water (15 degrees) and hot water (50 degrees) are used. The end of the tube is in contact with the desired point on the skin for 5 seconds and the patient is asked about the water temperature (hot or cold). Finally, after 10 tests, the number of correct answers is considered as the patient's score.

4

Description

score of sharp blunt discrimination

Timepoint

Day preoperative and then on days 1, 3, 7, 14, 21, 28 and 35 postoperative

Method of measurement

This test is performed using a dental explorer 17/23 to test the sharp sense and a periodontal probe for the blunt sense. One of these two tools contacts the target point with a gentle pressure and the patient is asked about its feeling of being sharp or blunt, and at the end, the number of correct answers is recorded from 10.

5

Description

score of visual analogue scale

Timepoint

Day preoperative and then on days 1, 3, 7, 14, 21, 28 and 35 postoperative

Method of measurement

The level of patient satisfaction with the restoration of sensation in the middle of the face is indicated by a number between 0 and 10.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the middle part of the face, on the intervention side, laser therapy will be done by an operator on days 1, 3, 7, 14, 21 and 28 after surgery, by GaAlAs diode laser device with wave length specifications of 810, power 250mW, in Continuous wave density energy density 12 J / cm² made by Konftec, Co, Taipei, Taiwan. 13 points (each point with an area of 0.5 cm² and for 24 seconds) will be irradiated from the upper lip vermilion to the ipsilateral zygoma. The handpiece of the laser device is in contact with the skin surface of the mentioned area and is applied with a little pressure. The patient will not feel any heat changes or pain during the laser treatment.

Category

Treatment - Devices

2

Description

Control group: The probe of the device is used on the control side with the same time as intended on the intervention side and in places similar to laser therapy points on the intervention side, in off mode.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Nima Dehghani

Street address

Sina hospital, Hasanabad Sq, Emam Khomeynei St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences- faculty of dentistry

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?**

No

Title of funding source

student

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

School of Dentistry (Tehran University of Medical Sciences)

Full name of responsible person

Nima Dehghani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

oral & maxillofacial surgery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Dentistry (Tehran University of Medical Sciences)

Full name of responsible person

Nima Dehghani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data file and statistical analysis will be shared.

When the data will become available and for how long

3 months after data collection

To whom data/document is available

The above information will be made available to the public in the form of appendices along with the published article.

Under which criteria data/document could be used

To better understand the study findings as well as a reference for future studies

From where data/document is obtainable

From the website of the journal in which the article will be published

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

The data file and statistical analysis will be available to everyone.

Comments
