

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of photobiomodulation on neurosensory disturbances after sagittal osteotomy of mandible

Protocol summary

Study aim

Evaluation of the effect of low level laser on sensory disturbances after mandibular orthognatic surgery

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 20 patients, from June 2018 for 6 months, including 20 patients

Settings and conduct

This double-blind randomized controlled trial was carried out on patients who were candidates of mandible orthognathic surgery and were referred to maxillofacial surgery ward of Sina and Shariati Hospitals affiliated to Tehran University of Medical Sciences, Iran.

Participants/Inclusion and exclusion criteria

patients included if underwent bilateral sagittal split mandibular ramus osteotomy. patients excluded if they reported underlying disease or past history of mandibular surgery.

Intervention groups

In intervention group laser used but in the control group the laser did not use.

Main outcome variables

neurosensory recovery; changes in visual analog scale (VAS) for general sensitivity; directional discrimination; 2-point discrimination; pain discrimination; thermal discrimination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190513043579N1**
Registration date: **2019-06-09, 1398/03/19**
Registration timing: **retrospective**

Last update: **2019-06-09, 1398/03/19**

Update count: **0**

Registration date

2019-06-09, 1398/03/19

Registrant information

Name

Mohammad mehdi Taheri

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-01, 1397/03/11

Expected recruitment end date

2019-01-31, 1397/11/11

Actual recruitment start date

2018-06-15, 1397/03/25

Actual recruitment end date

2019-01-15, 1397/10/25

Trial completion date

2019-03-15, 1397/12/24

Scientific title

Evaluation of the effect of photobiomodulation on neurosensory disturbances after sagittal osteotomy of mandible

Public title

Evaluation of the effect of low level laser on sensory disturbances after mandibular orthognatic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

no previous facial trauma or inferior alveolar nerve injury

no neurosensory disturbance before surgery patients underwent osteotomy to correct the maxillofacial deformity no consumption of analgesic, anticonvulsants and antidepressants medications

Exclusion criteria:

Patients with systemic diseases patients with bad split or severe bleeding during the surgery patients with obvious nerve damage during the surgery patients with neuromuscular disorders patients' candidate for genioplasty

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

Left and right side of every participant's mandible.

Actual sample size reached: **36**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Left and right side of every participant's mandible.

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers were generated through computerized block randomization using SPSS software version 23.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and doctor who evaluated neurosensory recovery were blinded to the side of laser radiation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dentistry school, Tehran University of Medical Sciences

Street address

North kargar St.

City

Tehran

Province

Tehran

Postal code

۱۳۳۹۹۵۵۹۹۱

Approval date

2018-04-23, 1397/02/03

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1397.080

Health conditions studied

1

Description of health condition studied

neurosensory disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

neurosensory recovery

Timepoint

assessment of neurosensory recovery 1 and 30 and 60 days after the surgery

Method of measurement

neurosensory tests

Secondary outcomes

1

Description

General Sense

Timepoint

assessment of General Sense 1 and 30 and 60 days after the surgery

Method of measurement

Visual Analogue Scale

2

Description

Pain Sensation

Timepoint

assessment of Pain Sensation 1 and 30 and 60 days after the surgery

Method of measurement

Needle gauge 23

3

Description

Two Point Discrimination

Timepoint

assessment of Two Point Discrimination 1 and 30 and 60 days after the surgery

Method of measurement

surgical compass

4

Description

Thermal discrimination

Timepoint

assessment of Thermal discrimination 1 and 30 and 60 days after the surgery

Method of measurement

Ethyl chloride spray

5

Description

directional discrimination

Timepoint

assessment of directional discrimination 1 and 30 and 60 days after the surgery

Method of measurement

Clinical test by nylon thread

Intervention groups

1

Description

Laser irradiation was applied with a GaAs diode laser (Wiser; Doctor Smile-Lambda Spa, Brendola, Vicenza, Italy) (980 nm wavelength, power of 100 mW, and the energy density of 12 J/cm²). Laser irradiation was maintained within a 0.5 cm² area. Laser energy was used for 60 sec in each visit. Unilateral extraoral LLL therapy was done one day before the surgery and then on the days 1, 3, 7, 14, 21, and 28 after the surgery. One side of the mandible was considered as the intervention side and the other side was considered as the control side. In the control side, laser probe with a red light was put on the considered area, but device was not activated, so that the patients were blinded to the side radiated by laser. In chin area, radiation was done on 6 points on each side from vermilion border to the lower border vertically and from midline to oral commissure horizontally. Then, radiation was applied on 6 points in buccal region from oral commissure to lingula with a gentle pressure of laser probe.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Taheri

Position

Resident

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

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