Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the of low-level laser photo biomodulation effect on enhancement of post Lefort I and sagittal split osteotomy surgery neurosensory deficits with clinical neurosensory testing (CNST)

Protocol summary

Study aim

Evaluation and comparison the mean values of quantitative neurosensory measurement after orthognatic surgury with low level laser in patients who want Lefort I and sagittal split osteotomy surgery in 12 patients(6female and 6 male)

Design

Clinical trials with a control group, with parallel groups, double-blind, randomized.6 patients in control group and 6 patients in Intervention group.

Settings and conduct

Patients candidates for orthognathic surgery in Alzahra and Kashani hospitals are informed about the study and after approval of inclusion criterias ,are entered to the study. After surgery(Lefort I and sagittal split osteotomy surgery), they are exposed to low level laser unilaterally and having the other side as control group with placebo effect of laser on stand-by mode with patient blinded to the side in 2 determined recalls after surgery, neurosensory changes are evaluated by clinical neurosensory tests(Thermal test,two point descrimination,light touch,pin prick)

Participants/Inclusion and exclusion criteria

Inclusion criteria:: healthy systemic status: age 18-30, healthy neurological system, informed consent, Patients candidate for orthognathic surgery. Exclusion criteria: Any local or systemic disease, age under 18 and over 30 years, history of trauma and jaw fracture, history of previous maxillofacial surgery,lack of cooperation,Pregnancy, Immune system defects, smoking, Taking muscle relaxant and sedative and anti-inflammatory drugs over the past 3 months.

Intervention groups

Control group: Orthognathic surgery without laser exposure. Intervention group: Orthognathic surgery then exposure using GaAlAs low level laser.

Main outcome variables

Quantitative neurosensory changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047026N1**
Registration date: **2020-05-11, 1399/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-11, 1399/02/22**
Update count: **0**

Registration date

2020-05-11, 1399/02/22

Registrant information

Name

Maryam Haghighat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 0107

Email address

maryamhhh806@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-12, 1398/11/23

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the of low-level laser photo biomodulation effect on enhancement of post Lefort I and sagittal split osteotomy surgery neurosensory deficits with clinical neurosensory testing (CNST)

Public title
Effect of low level laser therapy on paresthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy systemic status Age 18-30 Healthy neurological system informed consent Patients Candidate for orthognathic surgery

Exclusion criteria:
Any local or systemic disease Age under 18 and over 30 years History of trauma and jaw fracture History of previous maxillofacial surgery Taking muscle relaxant and sedative and anti-inflammatory drugs over the past 3 months Pregnancy Immune system defects Smoking Taking muscle relaxant and sedative and anti-inflammatory drugs over the past 3 months

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **12**
More than 1 sample in each individual
Number of samples in each individual: **4**
upper right jaw, upper left jaw, lower left jaw, lower right jaw

Randomization (investigator's opinion)
Randomized

Randomization description
Surgical areas (left or right) in each jaws (maxilla and mandible) are randomly divided into two groups (intervention and control) by coin flipping method.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each operated jaws of the patients (maxilla or mandible) are randomly divided to right and left sides as intervention or control side (with coin flip) then the patients are treated unilateral with laser on and the other side with laser off without awareness of knowing the on or off of the device. Then after 1,3 months they are evaluated bilaterally with clinical neurosensory tests by the person who dont know about intervention or control side.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Hezarjarib St.

City
Isfahan

Province
Isfehan

Postal code
8173955161

Approval date
2020-01-12, 1398/10/22

Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.602

Health conditions studied

1

Description of health condition studied
Post-orthognathic surgery paresthesia

ICD-10 code
R20.2

ICD-10 code description
Paresthesia of skin

2

Description of health condition studied
Jaw deformity

ICD-10 code
M26

ICD-10 code description
Dentofacial anomalies [including malocclusion]

Primary outcomes

1

Description
Thermal

Timepoint
Before surgery, 2 and 3 months after surgery

Method of measurement
Visual Analogue Scale

2

Description
light touch
Timepoint
Before surgery, 2 and 3 months after surgery
Method of measurement
Visual Analogue Scale

3

Description
Pin prick
Timepoint
Before surgery, 2 and 3 months after surgery
Method of measurement
Visual Analogue Scale

4

Description
Two point discrimination
Timepoint
Before surgery, 2 and 3 months after surgery
Method of measurement
caliper

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one side, called treated site will randomly choose for low level laser therapy by portable device (GaAlAs) in day 1, 5, 10 and 14 after orthognathic surgery. Exposure areas in lefort I candidates are 10 points in infra-orbital innervation entity between philtrum, lateral alar rim, lower lip, malar eminence and commissure lip line extension. exposure areas in mandible BSSO surgery are 7 points in IAN canal line between angle to menton (linear and 1 cm apart) and 9 points in mental erea (between mental foreman to midline).
Category
Treatment - Devices

2

Description
Control group: Orthognathic surgery without laser exposure. In the control group (other side) the device is in stand-by mode with no exposure (placebo effect) and the same points with the same duration are pretending to be irradiated as the treated side.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Taghi Hashemi
Street address
Kashani Ave.
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Isfahan
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Postal code
8183983434
Phone
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Email
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2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Majid Rezvani
Street address
Hezar Jrib Ave
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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
NakisaTorabinia
Street address
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Haghighat

Position

Dentistry Student

Latest degree

A Level or less

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