Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the low level laser photobiomodulation effect on post Lefort I and sagittal split osteotomy surgery neurosensory deficits enhancement with quantitative electrodiagnostic neurosensory test (blink reflex)

Protocol summary

Study aim
Evaluation and comparison the mean values of quantitative electrodiagnostic neurosensory measurement in the tread side with low level laser and the control side , before operation,30 and 90 days after orthognathic surgery

Design
Clinical trials with a control group, with parallel groups, double-blind, randomized.

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. The patients are asked to get electromyography (EMG) test of infraorbital and inferior alveolar nerve bilaterally by the aid of blink reflex to determine the neurosensory status quantitatively before surgery. After 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 with EMG.

Participants/Inclusion and exclusion criteria
Inclusion criteria:: healthy systemic status: age 18-30, healthy neurological system, Signature of consent form, 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, discontent to cooperation, Undesirable splint during operation, Pregnancy, Immune system defects, smoking, Taking muscle relaxant and sedative and anti-inflammatory drugs over the past 3 months, Failure to attend follow-up sessions.

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: **IRCT20191228045909N1**
Registration date: **2020-03-02, 1398/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-02, 1398/12/12**
Update count: **0**

Registration date
2020-03-02, 1398/12/12

Registrant information

Name
Alireza Tamizifar

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
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 low level laser photobiomodulation effect on post Lefort I and sagittal split osteotomy surgery neurosensory deficits enhancement with quantitative electrodiagnostic neurosensory test (blink reflex)

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 Signature of consent form 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 Undesirable splint during operation Pregnancy Immune system defects smoking Taking muscle relaxant and sedative and anti-inflammatory drugs over the past 3 months Failure to attend follow-up sessions
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

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 patienst are treated unilateral with laser on and the otherside with laser off without awareness of knowing the on or off of the device. then after 2,3 months they are evaluated bilaterally by the EMG technician without knowing the treated or placebo sides
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
Hezar Jerib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-01-07, 1398/10/17
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.601

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
The mean latency of R1, R2 and R2' (msec) in blink reflex electromyography
Timepoint
Before surgery, 2 and 3 months after surgery
Method of measurement
Blink reflex electromyography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one side, called treated site was randomly chosen 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 were 10 points in infra-orbital innervation entity between philtrum, lateral alar rim, lower lid, malar eminence and commissure lio line extension. exposure areas in mandible BSSO surgery were 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
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2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
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
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
Alireza Tamizifar
Position
Post Graduate

Latest degree
Medical doctor
Other areas of specialty/work
Oral and Maxillofacial Surgery
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Person responsible for updating data

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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