

# 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 GaAIs 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5512

##### Email address

alirezatamizifar@dnt.mui.ac.ir

##### 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 patient 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**

Isfahan

**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 area (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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8183983434

##### Phone

+98 31 3233 0091

##### Email

kashani@mui.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Al-Zahra Hospital

##### Full name of responsible person

Majid Rezvani

#### Street address

Hezar Jrib Ave

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3620 2020

#### Email

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

Hezar Jerib Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 5502

##### Email

pajouhesh@mui.ac.ir

#### 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

**Street address**

No. 5, Pasandideh Ave, East Allame Amini Blvd,  
Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8158935181

**Phone**

+98 31 3260 0885

**Email**

alirezatamizifar@dnt.mui.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Tamizifar

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**Latest degree**

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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