

# 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 orthognathic surgery 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**

Isfahan

**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 (GaAIs) 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 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**

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##### **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**

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##### **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 Jrib Ave.

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##### **Postal code**

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##### **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**

Maryam Haghighat

**Position**

Dentistry Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Full name of responsible person**

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**Position**

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**Latest degree**

A Level or less

**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**

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