

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effect of 660nm low level laser therapy on post-operative facial swelling, wound healing and pain

#### Protocol summary

##### Study aim

Determining the Effect of Using 660 Nm Low-Level Laser as a Method for Reducing Pain , swelling and Wound Healing after Orthognathic Surgery

##### Design

A clinical trial with control group , 12 people, with parallel groups, Triple blind, randomized,

##### Settings and conduct

A study was conducted in Kashani Hospital in Isfahan on patients undergoing Orthognathic surgeries. Lefort 1 and bilateral sagittal split osteotomy (BSSO) were performed for all patients. The upper and lower jaws were fixed by screws and plates, and the wounds were sutured. the laser was a low-power 660nm diode laser.

##### Participants/Inclusion and exclusion criteria

1. Age of the patient (between 18 and 40 years) 2 The absence of systemic diseases 3. Non-use of tobacco 4. Do not take medications that affect healing. 5. Surgery is performed by a surgeon. 6. Patient Satisfaction and Collaboration 7. Lack of systemic diseases or use of drugs that affect wound healing 8. No history of seizure, thyroid tumors, pregnancy, malignant tumors of the mouth for laser treatment 9. Does not have an asymmetric patient

##### Intervention groups

Twelve patients were randomly divided into two groups of six, the first group was laser treatment on the right side of the face, and the left side of the face, offered laser

##### Main outcome variables

Pain; swelling; Wound Healing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180312039060N3**

Registration date: **2019-05-13, 1398/02/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-13, 1398/02/23**

Update count: **0**

##### Registration date

2019-05-13, 1398/02/23

##### Registrant information

###### Name

Alireza Ebrahimpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 4326 0653

###### Email address

alireza.ebrahimpour.1996@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-07, 1398/01/18

##### Expected recruitment end date

2020-04-06, 1399/01/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of 660nm low level laser therapy on post-operative facial swelling, wound healing and pain

##### Public title

Effect of laser therapy on swelling, wound healing and pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

1. Age of the patient (between 18 and 40 years) The absence of systemic diseases Non-use of tobacco Do not take medications that affect healing Lack of systemic diseases or use of drugs that affect wound healing No history of seizure, thyroid tumors, pregnancy, malignant tumors of the mouth for laser treatment patient has not asymmetric

**Exclusion criteria:**

No patient willingness to continue cooperation in the study Post-surgical infection allergy In the event of an unwanted incident during operation such as bad fracture if you need Genioplasty with the action of Bimax

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **12**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples numbered 1-12. randomization done with True random generator software in Random.Org. In the software, at least 1 and maximum 12 were assumed. Then the software was used until six distinct and non-repetitive numbers were obtained. Patients with acquired numbers were placed in the first group and the rest were in the second group.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Patients have no idea what side of the face they are pushing for the laser and which side is precipitated when the laser is pushed out. The statistician was not aware of which side of the placebo and which side of the laser was exposed Measurement was carried out by an experienced person and aware of the measurement process that was unaware of the protocol and goals of the study

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Islamic Azad University Isfahan (Khorasgan) Branch

**Street address**

Esfahan - East Gey Street - Arghavanieh-Ethics committee of Islamic Azad University Isfahan (Khorasgan) Branch-

**City**

Khorasgan

**Province**

Isfahan

**Postal code**

4361043610

**Approval date**

2018-09-11, 1397/06/20

**Ethics committee reference number**

IR.IAU.KHUISF.REC.1397.073

**Health conditions studied**

**1**

**Description of health condition studied**

Pain, swelling, wound healing

**ICD-10 code**

S02

**ICD-10 code description**

Fracture of skull and facial bones

**Primary outcomes**

**1**

**Description**

pain

**Timepoint**

2,4,7 and 14 days after surgery

**Method of measurement**

Visual Analogue Scale

**2**

**Description**

wound healing

**Timepoint**

one and two weeks days after surgery

**Method of measurement**

Probing every scar in three points that divides the wound into 4 equal parts.

**3**

**Description**

sewlling

**Timepoint**

2 and 3 weeks and first, second and third month after surgery

**Method of measurement**

1) The distance between the tragus to the corner of the mouth 2) The distance between the tragus to the pogonion 3) The distance between the Gonion and the Kantus

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: 12 patients are randomly divided into 2 groups of six. In the first group the LASER therapy will be conducted on the right side of the face while on the left side it's pretended with the LASER being off on the wounded (ulcer) area. In the second group, the left side of the face will be under LASER therapy while the laser is off on the right side and is pretended to be used

### Category

Rehabilitation

2

### Description

Control group: other side of the mouth

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Kashani hospital

#### Full name of responsible person

Alireza Sadighi

#### Street address

Esfahan - East Gey Street - Arghavanieh-Ethics committee of Islamic Azad University Isfahan (Khorasgan) Branch-

#### City

isfahan

#### Province

Isfahan

#### Postal code

4613646136

#### Phone

+98 31 3535 4053

#### Email

arsadighi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Shapour Haj rasouliha

#### Street address

Esfahan - East Gey Street - Arghavanieh-Ethics committee of Islamic Azad University Isfahan

(Khorasgan) Branch-

#### City

Isfahan

#### Province

Isfahan

#### Postal code

۸۱۵۵۱-۳۹۹۹۸

#### Phone

+98 31 3535 4053

#### Email

info@khuisf.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Islamic Azad University

### 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 Sadighi

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dentistry

#### Street address

Esfahan - East Gey Street - Arghavanieh-Ethics committee of Islamic Azad University Isfahan (Khorasgan) Branch-

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#### Province

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۸۱۵۵۱۳۹۹۹۸

#### Phone

+98 31 3535 4053

#### Email

arsadighi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Sadighi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**Esfahan - East Gey Street - Arghavanieh-Ethics  
committee of Islamic Azad University Isfahan  
(Khorasgan) Branch-**City**

Isfahan

**Province**

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**Postal code**

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+98 31 3535 4053

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Alireza Ebrahimpour

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Azadegan 8/1

**City**

Amol

**Province**

Mazandaran

**Postal code**

46136

**Phone**

+98 11 4326 0653

**Fax****Email**

alireza.ebrahimpour.1996@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

all data

**When the data will become available and for how long**

after paper published

**To whom data/document is available**

all person

**Under which criteria data/document could be used**

no situation

**From where data/document is obtainable**

alireza sadigh 09143083724

**What processes are involved for a request to access data/document**

1 day

**Comments**