

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of 660nm low level laser therapy on level of jaw's lateral movement after orthognathic surgery

Protocol summary

Study aim

Determining the effect of using low power laser on the amount of lateral movements of the jaw after orthognathic surgery

Design

This study is a clinical trial with a control group, with parallel, double-blind, randomized groups on 12 patients who are candidates for orthognathic surgery. The study will be in the form of a split mouth. Random number table was used for randomization.

Settings and conduct

12 patients who are candidates for orthodontic surgery of the jaw are selected for the study. On a daily basis in 4 times immediately after surgery, two days later, four days later and one week after laser surgery. Low power with an output power of 50 mW and a dose of 5 joules per square centimeter is irradiated at the site of laser surgical incisions

Participants/Inclusion and exclusion criteria

1. Patient age (between 18 and 40 years) 3. Absence of systemic diseases 4. Do not use tobacco 5. Do not take drugs that affect healing. 6. Patients' surgery is performed by a surgeon. 7. Absence of systemic diseases or use of drugs effective in wound healing 8. No history of seizures Pregnancy thyroid tumors Malignant oral tumors for laser treatment 9. The disease does not have asymmetry

Intervention groups

Lefort 1 maxillary and bilateral sagittal split (BSSO) ostomy will be performed for all patients. The low power laser used is the 660 nm low power laser. In 12 patients, 6 of them are on the right side for laser treatment and the left side is off. In the remaining 6 patients, the left side is off for laser treatment and the right side is off.

Main outcome variables

Trismus and the amount of lateral movements of the jaw

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180312039060N4**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **prospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

Registration date

2020-11-28, 1399/09/08

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

2020-12-09, 1399/09/19

Expected recruitment end date

2021-04-17, 1400/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 660nm low level laser therapy on level of jaw's lateral movement after orthognathic surgery

Public title

Effect of laser therapy on level of jaw's movement after orthognathic surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of systemic diseases No smoking Do not take drugs that affect healing Patients' surgery is performed by a surgeon. Absence of systemic diseases, use of drugs effective in wound healing No history of seizures Pregnancy thyroid tumors Malignant oral tumors for laser treatment Do not have asymmetric disease Age range 18-40 years

Exclusion criteria:

The patient's unwillingness to cooperate in the study Infection after surgery Sensitivity or allergies In case of unwanted accidents during the operation, such as bad fracture If you need genioplasty with bimax operation (two jaws)

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were numbered from 1 to 12. Randomization was performed with the help of true random generator software at random.org. In this way, in the software, a minimum of 1 and a maximum of 12 were assumed. Then 6 distinct and non-duplicate numbers were taken from the software and the numbers were classified in the first group and other samples in the second group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In 12 patients, 6 of them are on the right side for laser treatment and the left side is off. In the remaining 6 patients, the left side is off for laser treatment and the right side is off.

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

2019-03-12, 1397/12/21

Ethics committee reference number

IR.IAU.KHUISF.REC.1398.006

Health conditions studied

1

Description of health condition studied

Trismus and the amount of lateral movements of the jaw

ICD-10 code

S02

ICD-10 code description

Fracture of skull and facial bones

Primary outcomes

1

Description

Trismus

Timepoint

Immediately after surgery, two days later, four days later and one week after surgery

Method of measurement

Using a ruler, the maximum opening of the patient's mouth is recorded and compared in the stated time periods.

2

Description

The amount of lateral movements of the jaw

Timepoint

Immediately after surgery, two days later, four days later and one week after surgery

Method of measurement

To evaluate postoperative trismus in patients, two days and seven days after surgery, we measure the lateral movements of the jaw to the right and the lateral movements of the left jaw to mm, and the deviation of the jaw when opening the mouth on the second, seventh days. And the fourteenth is measured

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 12 patients are randomly divided into two groups of 6, in the first group laser treatment is performed on the right side of the face and in the second group on the left side for laser treatment.

Category

Rehabilitation

2

Description

Control group: In the first group, the left side of the mouth will be used as a control, and the laser will be pretended to shine while it is off. In the second group, this action will be done on the right 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-

City

Esfahan

Province

Isfahan

Postal code

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

Esfahan

Province

Isfahan

Postal code

۸۱۵۵۱۳۹۹۹۸

Phone

+98 31 3535 4053

Email

arsadighi@gmail.com

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

blv Khazar, faculty of Dentistry

City

Sari

Province

Mazandaran

Postal code

12345-56987

Phone

+98 11 3355 6698

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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