Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of660nm 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)

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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 of660nm 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
Isfehan
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Shapour Haj rasouliha
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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
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
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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