

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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

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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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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences
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Latest degree
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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

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