Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, offed 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

Isfehan

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 dividied 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
Isfehan
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
Isfehan
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
Isfehan
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
Isfahan
Province
Isfehan
Postal code
4613646136
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
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