

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of Low Level Laser Therapy on edema ecchymosis and pain after Rhino plastic surgery

Protocol summary

Study aim

Determining the effect of low power laser in reducing pain, edema and ecchymosis following rhinoplasty in the Department of Oral and Maxillofacial Surgery of Azad Islamic Dental School of Tehran in 1402

Design

The study is a single-blind randomized clinical trial phase3 with 44 patients with the rand option of Excel software using the method of 4 randomized blocks of two intervention and control groups.

Settings and conduct

The number of 44 patients eligible for rhinoplasty for cosmetic or functional reasons were treated in the hospitals of Tehran Islamic Azad University of Medical Sciences in a one-sided blind randomized manner by a statistician. The person who measures the consequences of the intervention will be blind to the intervention.in intervention group patients will be divided into two control groups. The process of using the laser will be done in the private office of the supervisor. before and after surgery will be used

Participants/Inclusion and exclusion criteria

Inclusion criteria:surgery for cosmetic or functional reasons, absence of birth defects; Exclusion criteria: the presence of contraindications to the use of corticosteroids, hypertension and stomach ulcers, the presence of neurological and mental diseases, the presence of sensitivity or risk to the use of low-power lasers, a woman in the period of menopause.

Intervention groups

In all patients, 8 mg of dexamethasone will be used one hour before surgery, 24 hours and 48 hours after surgery, and antibiotic prophylaxis regimen including 500 mg of cephalexin will be used for 5 days, and only steroid analgesics will be Acetaminophen. The control group will only use the protocols mentioned above and in the intervention group, photobiomodulation therapy immediately after surgery and continue it 48 hours and 72 hours after surgery.

Main outcome variables

Reduction of edema, reduction of ecchymosis, reduction of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230515058195N1**

Registration date: **2023-05-29, 1402/03/08**

Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**

Update count: **0**

Registration date

2023-05-29, 1402/03/08

Registrant information

Name

Bardia Afshar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 3358

Email address

bardiaafshar123@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-12-07, 1402/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Low Level Laser Therapy on edema ecchymosis and pain after Rhino plastic surgery

Public title
Evaluation of Low Level Laser Therapy on edema ecchymosis and pain after Rhino plastic surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients in demand for rhinoplasty for functional or cosmetic reasons
Exclusion criteria:

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into intervention and control groups by using the rand option of Excel software and by the method of 4 blocks

Blinding (investigator's opinion)
Single blinded

Blinding description
The data allocation process was done by the statistical methodology consultant and other researchers are not aware of this process

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of Islamic Azad University, Dental Branch Tehran - Iran

Street address

Dental branch of Islamic Azad University of Tehran, 9th neyestan, Pasdaran, Tehran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.IAU.DENTAL.REC.1402.026

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Edema

Timepoint

7 day after surgery, 30 day after surgery

Method of measurement

Comparison of the distance between the two tips of the nose in the photos 7 and 30 days after the operation

2

Description

Echymosis

Timepoint

24 hours after surgery, 7 days after surgery, 30 days after surgery

Method of measurement

In the form of checking the distance between the eyelids in the photos before and after the operation and categorizing it as how much of the vertical line that passes through the eyelids and pupils is involved compared to the same before the operation.

3

Description

Pain

Timepoint

24 hours after surgery, 7 days after surgery, 30 days after surgery

Method of measurement

Using the Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will begin the full course of photobiomodulation therapy (PBMT) immediately after surgery and continue it for 48 hours and 72 hours after surgery.

Category

Rehabilitation

2

Description

Control group: Without receiving a low level laser therapy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

private practice

Full name of responsible person

Behnaz Poorian

Street address

next to Shariati Subway Station, Shariati

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 933 405 2223

Email

behnazpoorian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Behnaz Poorian

Street address

Dental branch of Islamic Azad University of Tehran,
9th neyestan, Pasdaran, Tehran

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

behnazpoorian@gmail.com

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

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Behnaz Poorian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Dental branch of Islamic Azad University of Tehran,
9th neyestan, Pasdaran, Tehran

City

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Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

behnazpoorian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Behnaz poorian

Position

Assistant Professor of Surgery Department, Azad
Faculty of Dentistry, Tehran

Latest degree

Specialist

Other areas of specialty/work

Oral and maxio facial surgion

Street address

Dental branch of Islamic Azad University of Tehran,
9th neyestan, Pasdaran, Tehran

City

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Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

behnazpoorian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Behnaz poorian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Province

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1946853314

Phone

+98 21 2256 4571

Email

benazpoorian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be published after the completion of the trial and the conclusion

When the data will become available and for how long

After the trial is over, the results will be announced

To whom data/document is available

After the trial is over, the results will be announced

Under which criteria data/document could be used

The responsible author and the people conducting the research will be allowed to analyze and review the data, use the data for statistical analysis, or use the results to determine the volume of similar studies.

From where data/document is obtainable

Email to the corresponding author email:
behnazpoorian@gmail.com Address: Nistan 9th,
Pasdaran, Tehran, Azad Islamic Faculty of Dentistry,
Department of Oral, Maxillofacial Surgery Postal code:
1946853314 Phone number: 009802122763460

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

Calling and emailing the responsible author while specifying the reason for the data request along with determining how to use the results and specifying the type of analysis required for the requester. If the requester is qualified, they will respond as soon as possible

Comments