

# 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

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##### 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

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9th neyestan, Pasdaran, Tehran

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**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**

Dentistry

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**Phone**

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**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**