

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the Effect of light emitting diodes therapy (LEDT) to Reduce the Recovery Period of Rhinoplasty

#### Protocol summary

##### Study aim

If significant effectiveness is observed, low power laser can be a low cost and effective way to reduce the duration of patient involvement after rhinoplasty.

##### Design

A clinical trial with a control group, with parallel, randomized groups, on 20 patients. Data are analyzed using SPSS software (version 26). Quantitative variables with mean and variance and qualitative variables with frequency and percentage are described. Independent t-test, Mann-Whitney and chi-square tests are used to compare the two groups. Paired t-test, Wilcoxon and Mac Nemar tests are used for group comparison. Significance level less than 0.05 is considered

##### Settings and conduct

In a randomized blinded clinical trial, patients referred to the hospital for rhinoplasty are evaluated for inclusion criteria. Treatment procedure in the case group of 660 nm low power diode laser device with a dose of 4 joules per square centimeter, continuous 10 sessions Evaluations are performed once before assigning patients to treatment groups and once at the end of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: age range between 30 to 70 years and complete satisfaction to participate in the study. with diabetes, pregnant and lactating women, photosensitivity, under 30 years and over 70 years, history of seizures and secondary hypertension are excluded from the study.

##### Intervention groups

660 nm low power diode laser device treatment procedure with a dose of 4 joules per square centimeter, continuous 10 sessions every other day for 20 days Both the control and case groups are treated routinely. Treatment in this group will also be given by the same doctor.

##### Main outcome variables

Age; sex; underlying diseases; Disease duration; Laser

power; Laser wavelength; Frequency of irradiation; Duration of bruising; Duration of pain relief; Duration of swelling reduction; Duration of wound healing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111121008146N36**

Registration date: **2021-11-24, 1400/09/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-24, 1400/09/03**

Update count: **0**

##### Registration date

2021-11-24, 1400/09/03

##### Registrant information

##### Name

Mohammadreza Razaghi

##### Name of organization / entity

Laser application in medical sciences research center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2271 8021

##### Email address

laser.cntr@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-11-22, 1401/09/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Effect of light emitting diodes therapy (LEDT) to Reduce the Recovery Period of Rhinoplasty

**Public title**

Evaluation of the Effect of light emitting diodes therapy (LEDT) to Reduce the Recovery Period of Rhinoplasty

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range between 30 and 70 years Complete consent to participate in the study

**Exclusion criteria:**

Diabetes Pregnant and lactating Sensitivity to light Under 30 and over 70, History of seizures and hypertension in the disease (secondary hypertension)

**Age**

From **30 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All patients are divided into case and control groups according to the table of random numbers with a ratio of 1: 1. The assigned group of individuals is placed one after the other in dark envelopes

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics in Biomedical Research of Shahid Beheshti University of medical sciences

**Street address**

Daneshjoo Blvd, Yaman street

**City**

tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2021-09-19, 1400/06/28

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.355

**Health conditions studied****1****Description of health condition studied**

Rhinoplasty

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

pain

**Timepoint**

After surgery, Three days later, one week later, ten days later and 15 days later

**Method of measurement**

VAS

**2****Description**

Ecchymosis

**Timepoint**

After surgery, Three days later, one week later, ten days later and 15 days later

**Method of measurement**

Based on the review of daily photos, we divide them into the following categories: no ecchymosis, mild ecchymosis, moderate and severe

**3****Description**

Swelling

**Timepoint**

After surgery, Three days later, one week later, ten days later and 15 days later

**Method of measurement**

Based on the review of daily photos, we divide them into the following categories: no swelling, mild, moderate and severe swelling

**4****Description**

Wound healing

**Timepoint**

After surgery, Three days later, one week later, ten days

later and 15 days later

#### **Method of measurement**

Based on the comparison of incision wounds

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: 660 nm low power diode laser device treatment procedure with a dose of 4 joules per square centimeter, continuous 10 sessions every other day for 20 days

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Control group: Patients in this group are treated routinely. Treatment in this group will be given by the same doctor

##### **Category**

N/A

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Central City Clinic

###### **Full name of responsible person**

Behrouz Barikbin

###### **Street address**

No. 20 and 24,Valinejad St,Vanak Square, Tehran

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1969853831

###### **Phone**

+98 21 8888 4425

###### **Email**

Dr.barikbin@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Sadi Banar

###### **Street address**

Laser Application in Medical Sciences Research

Center, Shohadaye-Tajrish Educational Hospital,  
Tajrish Sq, Tehran, Iran

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1989934370

###### **Phone**

+98 21 2271 8021

###### **Email**

laser.cntr@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Shahid Beheshti University of Medical Sciences

##### **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**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Maryam Barati

###### **Position**

General Practitioner

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

General Practitioner

###### **Street address**

Laser Application in Medical Sciences Research  
Center, Shohadaye-Tajrish Educational Hospital,  
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### **Person responsible for scientific**

## **inquiries**

### **Contact**

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## **Person responsible for updating data**

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## **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**

All data is potentially shareable after unidentified individuals

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Researchers and Rhinosurgeons

**Under which criteria data/document could be used**

Email the corresponding author and earn permission

**From where data/document is obtainable**

Email the corresponding author

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

Email the corresponding author, the authors' meeting, send the data at your discretion

**Comments**