

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluation the effect of low level laser therapy with 940 nm wavelength Diode laser on the reduction of post operative scar: a double blind prospective clinical trial study

#### Protocol summary

##### Study aim

Evaluation the effects of 940 nm low level diode laser therapy on post operative scar, a clinical trial study

##### Design

Clinical trial with control group

##### Settings and conduct

14 Patients who are candidate for elective bilateral facial surgery will be enrolled in the study. They receive bilateral incision, one side irradiated by laser , as case group, and the other one considered as control. Nobody is aware about case and control sides except person who irradiate laser. 4 days after surgery, on suture removal visit (8 days after surgery) and then after two times a week until a month the location of the incision will be irradiated. Scars will be evaluated on 1st and 6th months after surgery. laser setting is done to have 4 j/cm<sup>2</sup> energy density, 160mw/cm<sup>2</sup> power density, 1.5 watt power which is irradiated on a 6.9cm<sup>2</sup> area equivalent to 40 J for 26 seconds. For scar evaluation we use Vancouver analogue scale scoring between 0-13. the higher score is contributed to severe scar.

##### Participants/Inclusion and exclusion criteria

In the present study 14 patients who are candidates for bilateral elective facial surgery will be recruited after signing informed consent.

##### Intervention groups

Patients who are candidate for elective bi lateral surgery will be enrolled in the study. They receive bilateral incision the one side irradiated by laser and the other considered as control.

##### Main outcome variables

Scar severity

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170919036285N2**

Registration date: **2019-03-18, 1397/12/27**

Registration timing: **retrospective**

Last update: **2019-03-18, 1397/12/27**

Update count: **0**

#### Registration date

2019-03-18, 1397/12/27

#### Registrant information

##### Name

mina jazaeri

##### Name of organization / entity

Oral Medicine Department

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1059

##### Email address

m.jazaeri@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-07-23, 1397/05/01

#### Expected recruitment end date

2018-08-06, 1397/05/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effect of low level laser therapy with 940

nm wavelength Diode laser on the reduction of post operative scar: a double blind prospective clinical trial study

**Public title**

Effect of low level laser therapy on post operative scar

**Purpose**

Supportive

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

Patients who sign informed consents form Those who are candidate for bilateral elective facial surgery

**Exclusion criteria:**

patients with congenital and acquired dermal diseases  
Diabetes Phenytoin consumption Chemotherapy  
Radiotherapy Any other diseases which may affect wounds healing

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **14**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple, before laser irradiation we will use a coin to decide the side of irradiation. If the numeric side appears, the right side will be irradiated and vise versa.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In the present study the field of surgery in one side irradiated by laser but the other one receive placebo. The person who is responsible for irradiation is the only one who is aware about the side of placebo and laser irradiation. So patients, surgeon, nurses and assistants of surgery department, surgeon who assess the scar and statistical analyzer are not aware about placebo side.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Hamadan University of Medical Sciences

**Street address**

Shahid Fahmideh Blvd, Hamadan University of Medical Sciences, Vice-Chancellor for Research and Technology, Ethics committee

**City**

Hamadan

**Province**

Hamadan

**Postal code**

654178-38741

**Approval date**

2017-05-27, 1396/03/06

**Ethics committee reference number**

IR.UMSHA.REC.1396.171

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

scar

**ICD-10 code**

L90.5

**ICD-10 code description**

Scar conditions and fibrosis of skin

**Primary outcomes****1****Description**

Scar severity according to VAS

**Timepoint**

Scar evaluation 1 and 6 months after surgery

**Method of measurement**

VAS scor

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: in this group 940 nano meter diode laser, made by BIOASE company of the USA, is used. Irradiation is done on 4th and 8th day after surgery and then after 2 times a week for a month.

**Category**

Treatment - Other

**2****Description**

Control group: Laser machine in ready for use status, precisely similar to intervention group will be placed on incision place but no irradiation will be done.

**Category**  
Placebo

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Hamadan Besat Hospital  
**Full name of responsible person**  
Masih Moosavi Seresht  
**Street address**  
Shahid Beheshti Blvd  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517865123  
**Phone**  
+98 81 3264 0030  
**Email**  
besat@umsha.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Vice-chancellor for Research and Technology  
**Street address**  
Shahid Fahmide Blvd  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6516765087  
**Phone**  
+98 81 3838 0130  
**Email**  
research@umsha.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Hamedan 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. mina jazaeri  
**Position**  
Assistant professor of oral Medicine  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Department of Oral Medicine, School of Dentistry,  
Shahid Fahmide Blvd., Hamadan, Iran.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6515565687  
**Phone**  
+98 81 3838 1059  
**Fax**  
**Email**  
m.jazaeri@umsha.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. mina jazaeri  
**Position**  
Assistant professor of oral Medicine  
**Latest degree**  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Dr. mina jazaeri

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**Latest degree**

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6515565687

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+98 81 3838 1059

**Fax****Email**

m.jazaeri@umsha.ac.ir

**Web page address**

## 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 could be shared

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

it is reachable after article publication

**To whom data/document is available**

It is reachable for researchers.

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

According to the cases of other researchers will be decided

**From where data/document is obtainable**

via the email address m.jazaeri@umsha.ac.ir

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

6 months after publication by sending email and defining the the cooperation protocol, after 2 weeks data is reachable

**Comments**