

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/cm² energy density, 160mw/cm² power density, 1.5 watt power which is irradiated on a 6.9cm² 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
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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
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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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Full name of responsible person

Dr. mina jazaeri

Position

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Latest degree

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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