Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of low power laser on reducing preorbital ecchymosis after rhinoplasty in patients admitted in facial plastic surgery clinic

Protocol summary

Study aim
The aim of this study is to evaluate the effect of low-power laser in reducing bruising around the eyes after rhinoplasty.
Design
patients are randomly assigned to two groups of control and intervention by using of block randmization
Settings and conduct
All patients referred to Facial Plastic Surgery Clinic was undergoing rhinoplasty
Participants/Inclusion and exclusion criteria
Patients undergoing rhinoplasty are included in study , excluded cases were who need to re operation, patients with systemic disease, or congenital malformation or skin disease that this situations known as contraindications for laser using.
Intervention groups
low power laser used for reducing of edema and bruising after rhinoplasty in intervention group and no intervention used rhinoplasty in control group
Main outcome variables
periorbital ecchymosis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080820001056N3**
Registration date: **2019-01-04, 1397/10/14**
Registration timing: **retrospective**

Last update: **2019-01-04, 1397/10/14**
Update count: **0**
Registration date
2019-01-04, 1397/10/14

Registrant information

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Recruitment status
Recruitment complete
Funding source
Tehran university of medical science

Expected recruitment start date
2017-08-15, 1396/05/24
Expected recruitment end date
2018-08-20, 1397/05/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of low power laser on reducing preorbital ecchymosis after rhinoplasty in patients admitted in facial plastic surgery clinic

Public title
Effect of low power laser on reducing preorbital ecchymosis after rhinoplasty in patients admitted in facial plastic surgery clinic
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to Facial Plastic Surgery Clinic undergoing rhinoplasty

Exclusion criteria:
history of previous surgery systemic disease, congenital malformation skin disease, which contraindicates the use of laser radiation.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is 4block numbers

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
Ethical committee of Tehran university of medical science

Street address
Tehran university of medical science, Qods st., Keshavarz blvd., Tehran

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1417653761

Approval date
2017-08-15, 1396/05/24

Ethics committee reference number
IR.TUMS.VCR.REC.1396.3211

Health conditions studied

1

Description of health condition studied
periorbital ecchymosis

ICD-10 code
S00.1

ICD-10 code description
Contusion of eyelid and periocular area

Primary outcomes

1

Description
rate of periorbital ecchymosis based on the doctor's evaluation

Timepoint
before intervention, one week after intervention

Method of measurement
based on the doctor's evaluation by grading system (0-4)

2

Description
periorbital ecchymosis based on the patient’s evaluation

Timepoint
before intervention, one week after intervention

Method of measurement
based on the patient’s evaluation by VAS (1-10)

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: treatment with low power laser the day after surgery for 15 minutes over nose and face. was made by Meditex company, Canada

Category
Treatment - Other

2

Description
Control group: no intervention

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex

Full name of responsible person
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1

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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
Tehran 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

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
We will published it in article
When the data will become available and for how long
We will published it in article 2018
To whom data/document is available
nobody can have anything more than article
Under which criteria data/document could be used
We will published it in article, but nobody have access to other data
From where data/document is obtainable
We will published it in article
What processes are involved for a request to access data/document
contact with researchers
Comments