

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Diode 940 nm laser on reduction of post-rhinoplasty nasal tip edema

Protocol summary

Study aim

Evaluation of the effect of Diode 940 nm on post-rhinoplasty nasal tip edema after 2 months

Design

A concealed with sealed Envelope, randomized by quadri-blocks, blinded, sham controled clinical trial with a paraallel group design of 30 patients.

Settings and conduct

Patients will be assigned to study and control groups via four blocks. Surgical technique in both groups is open(Transcolumellar incision+Bilateral marginal incision). All surgeries will be performed by a oromaxillofacial surgeon. 940 nm diode laser is continuously exposed to eight ereas of nose, around of the nose, two nostrils and Submandibular and jugular-digastric areas. radiations will be performed by the thesis student. Angle measurements will be done by Adobe Photoshop from photographies. The device will be turned off in control group and the handpiece will be moved on nose and nostrils. A headphone will be put on both groups of patients during radiation.

Participants/Inclusion and exclusion criteria

This study will be conducted on patient who is a primary rhinoplasty candidate and is in ASA I grade (with no history of systemic disease); Patients with nasal and lip cleft, patients undergoing drug therapy, patients with a history of previous nasal surgery, and patients who do not take post-operative photographies will be excluded.

Intervention groups

940nm diod laser(Biolase, USA) will be radiated on patient's face; on eight areas of the nose and around it and also on submandibular and jugular-digastric areas. Laser radiation will be continuous. ray will be exposed to each area for 91 seconds. In the control group (Sham laser group), the device will be turned off and the handpiece will be moved on the nose and nasal holes. Meanwhile, at the time of laser and sham laser radiation, headphones will be placed on the ears of the patient.

Main outcome variables

reduction of nose tip edema; no reduction of nose tip edema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216041994N1**

Registration date: **2019-03-20, 1397/12/29**

Registration timing: **prospective**

Last update: **2019-03-20, 1397/12/29**

Update count: **0**

Registration date

2019-03-20, 1397/12/29

Registrant information

Name

Hanie Tavasoliara

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Diode 940 nm laser on reduction of post-rhinoplasty nasal tip edema

Public title

Evaluation of the effect of Diode 940 nm on reduction of nasal tip edema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

primary rhinoplasty candidate ASA I patients (no systemic disease)

Exclusion criteria:

Patients with lip and nasal cleft Patients under pharmaceutical treatment Patients with the history of rhinoplasty

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into Intervention and control group via quadri-blocks. concealment will be done through Sealed Envelope

Blinding (investigator's opinion)

Single blinded

Blinding description

In the control group (Sham laser group), the device will be turned off and the handpiece will be moved on the nose and nasal holes. Meanwhile, at the time of laser and sham laser radiation, headphones will be placed on the ears of the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamedan University of Medical

Sciences

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Hamedan university of medical sciences, Shahid Fahmideh Blvd., Hamedan Town

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6517838677

Approval date

2019-02-28, 1397/12/09

Ethics committee reference number

IR.UMSHA.REC.1397.877

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

nose tip edema after rhinoplasty

ICD-10 code

R60.0

ICD-10 code description

Localized edema

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

nose tip edema

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop software

Secondary outcomes**1****Description**

nose tip projection

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

2**Description**

supratip depression

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

3

Description

amount of Columella exposure

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

4

Description

nose tip retraction

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

5

Description

nasal width in middle of Columella

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

6

Description

nasal width in pinnacle of nostrils

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

7

Description

nasal width between pinnacle of nostrils and nose tip

Timepoint

8 days after surgery; every week until 2 months after surgery

Method of measurement

photoshop

Intervention groups

1

Description

Intervention group: 940nm Diod laser(Biolase,USA) is radiated to patient's face on eight zones of nose and nasal nostrils and also on Submandibular and jugular-digastric. Laser radiation will be continuous. Energy density: 4 J/cm², spot size: 2.27 cm², outputpower: 0.1 mW and the ray is radiated to each zone for 91 seconds. energy in each zone is 9.08 j. power density: 44 mW/cm²

Category

Treatment - Devices

2

Description

Control group: In control group(Sham laser group) the device will be turned off and the handpiece will be moved on nose and nasal nostrils.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr Mohammadreza Jamalpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellors of Research and Technology,
Hamedan University of Medical Sciences

Full name of responsible person

Maryam Asgarinia

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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

Vice-chancellors of Research and Technology, 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
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Hanie Tavasoliara

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available