

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of clinical outcomes and satisfaction of rhinoplasty with or without SMASectomy with the aim of thinning the nasal tip in patients with thick nasal skin

Protocol summary

Study aim

Improving the outcome of rhinoplasty surgery

Design

Double-blind, randomized clinical trial with a control group. A study on 70 patients who were randomly divided into two groups

Settings and conduct

Patients with thick skin in the nasal area after cosmetic surgery are not completely satisfied with the result of the operation, but with this method. This includes thinning the skin at the tip of the nose, which may improve patient satisfaction. The study is performed on patients in Isfahan hospitals. Patients are randomly divided into two groups, in one group the intervention and in the control group the intervention is not performed to thin the skin.

Participants/Inclusion and exclusion criteria

Admission requirements: Minimum age 18, Candidate for rhinoplasty surgery, Thick nasal skin, Informed consent. Exclusion criteria: history of rhinoplasty, history of smoking

Intervention groups

Patients in the control group are operated as usual , and the intervention group is operated by removing adipose tissue and muscle behind the skin of the tip of the nose.

Main outcome variables

Variables include skin thickness, postoperative satisfaction, and complications such as bleeding, skin necrosis, edema, scarring, and postoperative infection.

General information

Reason for update

An update was performed to complete the last patient visit.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210921052537N1**

Registration date: **2021-10-30, 1400/08/08**

Registration timing: **retrospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **1**

Registration date

2021-10-30, 1400/08/08

Registrant information

Name

Mehdi Rasti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 8506

Email address

mh_rasti@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2021-12-01, 1400/09/10

Actual recruitment start date

2021-09-23, 1400/07/01

Actual recruitment end date

2021-10-12, 1400/07/20

Trial completion date

2022-01-27, 1400/11/07

Scientific title

Evaluation of clinical outcomes and satisfaction of rhinoplasty with or without SMASectomy with the aim of thinning the nasal tip in patients with thick nasal skin

Public title

Evaluation of the effect of thinning of the tip of the nose on rhinoplasty in patients with thick skin

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who come for rhinoplasty Patients have thick nasal skin Patients are at least 18 years old Patients who have given informed consent

Exclusion criteria:

Those who smoke Those who have a history of rhinoplasty

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Patients who go for rhinoplasty and have thick skin are divided into two groups by permuted block randomization method and the patient does not know the type of operation. After the operation, the result is examined by four groups, the beautician, the patient, the cosmetic nurse, and another plastic surgeon who does not know the type of operation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of esfahan University of Medical Sciences

Street address

Unit.7,No.532, Dadsetan alley,Charbagh balla street, Azadi square

City

Esfahan

Province

Isfahan

Postal code

8163914396

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.MUI.MED.REC.1400.491

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

Rhinoplasty

ICD-10 code

Z41.1

ICD-10 code description

Encounter for cosmetic surgery

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

Postoperative satisfaction

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Satisfaction questionnaire,Photograph and collis

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

Bleeding

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Patient examination and photo

2**Description**

Edema

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Patient examination , photo and collis

3**Description**

Scare

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Patient examination and photo

4

Description

Necrosis

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Patient examination and photo

Intervention groups

1

Description

Intervention group: The skin of the tip of the nose
Patients becomes thin during rhinoplasty

Category

Treatment - Surgery

2

Description

Control group: Patients undergo rhinoplasty without
thinning the skin at the tip of the nose

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Esmaeil Talebian

Street address

Alzahra Hospital, Shohada sofhe Street

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Postal code

8174675731

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+98 31 3620 2020

Email

drtalebian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

DBeheshte Toghiani

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Unit. 7, No. 532, Dadsetani Alley, Charbagh bala Street,
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Esmaeil Talebian

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Esmail Talebian

drtalebian@yahoo.com

Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

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Full name of responsible person

Esmail Talebian

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Plastic Surgery

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Email

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

A clinical trial report will be available for subscription, including gender, age, procedure, and postoperative information for each individual and postoperative outcome.

When the data will become available and for how long

Start access one year after the results are published

To whom data/document is available

Clinical study reports are only available to plastic surgeons

Under which criteria data/document could be used

Using reports from clinical studies to conduct research on rhinoplasty techniques can be used by citing the source.

From where data/document is obtainable

Esmail Talebian ,email: drtalebian@yahoo.com

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

The applicant will receive a clinical study report after sending an email and explaining the reason for the need for the data, and future research of the applicant, after 10 days the information will be sent to him by email.

Comments