

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluating the effectiveness of the modified lateral crural strut graft on the aesthetic indices of the nasal tip in rhinoplasty

Protocol summary

Study aim

Evaluating the effectiveness of the modified lateral crural strut graft on the aesthetic indices of the nasal tip in rhinoplasty

Design

Pre- and post-intervention clinical trial, non-randomized, not blind

Settings and conduct

Thirty patients who referred to the ENT ward of Amir Alam hospital for septorhinoplasty operation were selected and divided into two groups of crural strut graft with classic method; and crural strut graft with modified method group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who undergo rhinoplasty for the first time; adult over 18 years old; Patients with parenthesis tip deformities; Exclusion criteria: Patients with immunological and metabolic diseases; Patient dissatisfaction; Pre and post-photography in two different ateliers; Failure to refer for photographing; Patients with cleft lip and plate

Intervention groups

The Intervention group 1: Patients with crural strut graft with classic method; The Intervention group 2: Patients with crural strut graft with modified method

Main outcome variables

Nasal tip in rhinoplasty; Tip bifidity; Double break; Supra tip break; Tip width to nasal width

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009039N6**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **retrospective**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

Registration date

2019-12-23, 1398/10/02

Registrant information

Name

Shahin Bastaninezhad

Name of organization / entity

Dep. ENT, AmirAlam Hospital

Country

Iran (Islamic Republic of)

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+98 21 6676 0269

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shahinbastani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of the modified lateral crural strut graft on the aesthetic indices of the nasal tip in rhinoplasty

Public title

Evaluating the effectiveness of the modified graft on the aesthetic indices of the nasal tip

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who undergo rhinoplasty for the first time Adult over 18 years old Patients with parenthesis tip deformities.

Exclusion criteria:

Patients with immunological and metabolic diseases Patient dissatisfaction Pre and post photography in two different studios Failure to refer to the photographer Patients with cleft lip and plate

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization type is blocked randomization. Foursquare blocks of intervention group(A) and control(B) are defined on cards 1-6 (AABB,ABAB,ABBA,BBAA,BABA,BAAB), the cards are placed inside the envelope. Then the cards are selected randomly and then the random string is created from the sequence of selected cards. Patients in the intervention and control group are included in the study according to this sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

None of the participants and researchers will be aware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-08-02, 1398/05/11

Ethics committee reference number

IR.TUMS.VCR.REC.1398.453

Health conditions studied

1

Description of health condition studied

rhinoplasty

ICD-10 code

R84

ICD-10 code description

Abnormal findings in specimens from respiratory organs and thorax

Primary outcomes

1

Description

tip plasty

Timepoint

6 months after surgery

Method of measurement

Photography before and after surgery

Secondary outcomes

1

Description

Tip bifidity

Timepoint

6 months after surgery

Method of measurement

Photography before and after surgery

2

Description

Double break

Timepoint

6 months after surgery

Method of measurement

Photography before and after surgery

3

Description

Supra tip break

Timepoint

6 months after surgery

Method of measurement

Photography before and after surgery

4

Description

Tip width to nasal width

Timepoint

6 months after surgery

Method of measurement

Photography before and after surgery

Intervention groups

1

Description

The intervention group: Under the dome and inferior border of lower lateral cartilage is dissected, modified strut cartilage will be fixed under the dome and inferior border of lower cartilage. At the end of the surgery it will be then repositioned into the rim of the pocket. With this approach after the transdomal suture the subdomal graft will help in new dome shaping. Therefore, the additional length will help in firming and ideal forming of alas.

Category

Treatment - Surgery

2

Description

Control group: In this group the usual method of tip plasty will be performed and only the inferior border of lower lateral cartilage will be dissected and the usual graft will be fixed under the lower, the lateral part of graft will be positioned in the pocket of rim to maintain the stability of the rim.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam hospital

Full name of responsible person

Hakima Abdullah

Street address

North Saadi St, AmirAlam Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hakima Abdullah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

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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

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

Data Dictionary

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