

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the correction of "acute nasolabial angle" and "columellar retraction" in two methods "caudal extension graft" and "columellar strut with plumping graft" in open rhinoplasty surgery

Protocol summary

Summary

1-Objectives: In this study we compare two methods which are used for the correction of tip among patients who have ptotic tip disorder. The target group of patients suffer acute nasolabial angle and columellar retraction where acute nasolabial angle refers to a nasolabial angle less than 90 degrees in men and a nasolabial angle less than 95 degrees in women, and columellar retraction is the columella size less than 3 millimeters. The study has two objectives. The first one is to compare correction ratio of nasolabial angle in two methods including "caudal extension graft" and "columellar strut with plumping graft". The second objective is to compare the amount of columella size correction achieved by these techniques. 2-Design, procedure, and intervention: In this study, 74 patients participated who were 18-40 years old and admitted for open rhinoplasty. The patients were randomly divided into two groups where each group was treated with a different tip surgery method. One group was treated by "caudal extension graft", and for the other group "columellar strut with plumping graft" was performed. We evaluated the result of the techniques 9 months after the operations. The standard face photograph before the operation and 9 months after the operation were taken. The preoperative and the postoperative standard photographs were evaluated by a physician who was unaware of the method which was used for the treatment of the patient. The physician measured nasolabial angle and columella size. Finally, the measurement data will analyze using statistical software. 3-Variables: A)preoperation nasolabial angle: B)postoperation nasolabial angle: C)preoperation columella size: D)Postoperation columella size.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102211215N1**

Registration date: **2014-01-24, 1392/11/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-24, 1392/11/04

Registrant information

Name

Saeid Atighechi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences and Health Service
Mrtyr Sadoughi, vice chancellor for research

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the correction of "acute nasolabial angle" and "columellar retraction" in two methods "cuadal extension graft" and "columellar strat with plumping graft" in open rhinoplasty surgery

Public title

Comparison of the correction of "acute nasolabial angle" and "columellar retraction" in two methods "cuadal extension graft" and "columellar strat with plumping graft" in open rhinoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age group 18-40 years; nasolabial angle less than 90 degrees in male and less than 95 degrees in female; columella show less than 3 mm.

Exclusion criteria: The patients disagreement; revision rhinoplasty; patients with poor coordination for fallow-up

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shahid Sadoughi University of Medical Sciences and Health Services

Street address

The Central Organization of Medical Sciences and Health Services Martyr Sadoughi, Martyr Dr Bahonar Square

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Approval date

2012-06-20, 1391/03/31

Ethics committee reference number

p/17/1/42803

Health conditions studied

1

Description of health condition studied

Follow-up care involving plastic surgery of open rhinoplasty

ICD-10 code

Z42.0

ICD-10 code description

Follow-up care involving plastic surgery of head and neck

Primary outcomes

1

Description

Nasolabial angle

Timepoint

pre and postoperation

Method of measurement

calculating the degree by a computer software

2

Description

columella show

Timepoint

pre and postoperation rhinoplasty surgery

Method of measurement

mm by calliper

Secondary outcomes

1

Description

patient satisfaction

Timepoint

after surgery

Method of measurement

chek list

Intervention groups

1

Description

cuadal extension graft method

Category

Treatment - Surgery

2

Description

columellar strut with plumping graft method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoughi Hospital

Full name of responsible person

Dr. Batoolsadat Sadjadinejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Associate dean for research and innovation, Shahid Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

Dr. Fatemeh Ezoddini

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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

Associate dean for research and innovation, Shahid Sadoughi University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty