

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The correction of nasal septal deviations in rhinoplasty: a novel approach using swing door technique with and without cartilage graft

Protocol summary

Study aim

The aim of this study is to compare septal deviation correction and patient's satisfaction between two groups of septoplasty with and without graft

Design

This study will be conducted on totally 40 patients in two groups of intervention and control using block randomization and double blinded methods.

Concealment will be carried out using pocket concealment.

Settings and conduct

The study will be conducted in Dey Limited Surgery Center affiliated to Arak University of Medical Sciences. Routine treatments before and after surgery were the same for two groups and only the details of the surgery technique is different between groups. The patient and outcome assessor are blinded regarding the group of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nasal septum deviation, patient's satisfaction for participation, age between 18-50 years;

Exclusion criteria: Drug allergies, respiratory diseases

Intervention groups

Intervention group: The surgical procedure performed under general anesthesia and one or more batten grafts made of septal cartilage is interposed between the cut ends of the caudal L-strut and then sutured. After surgery medications and follow-up are the same in both groups and are those routinely conducted in septoplasty. Control group: The surgical procedure performed under general anesthesia and deviated septum is interposed only using swing door technique without graft. After surgery medications and follow-up are the same in both groups and are those routinely conducted in septoplasty.

Main outcome variables

Nasal septum deviation; Patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170316033094N3**

Registration date: **2021-11-11, 1400/08/20**

Registration timing: **retrospective**

Last update: **2021-11-11, 1400/08/20**

Update count: **0**

Registration date

2021-11-11, 1400/08/20

Registrant information

Name

Mehdi Heidarizadeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6104

Email address

heidarizadeh.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-01, 1400/02/11

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The correction of nasal septal deviations in rhinoplasty: a novel approach using swing door technique with and without cartilage graft

Public title

Cartilage graft for correction of nasal septum deviation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Nasal septum deviation Patient's satisfaction for participation Age between 18-50 years

Exclusion criteria:

Drug allergies Respiratory diseases

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups using the block randomization method with the following sequences: AABB, ABAB, ABBA, BAAB, and BABA. Group A undergoes the swing door without cartilage graft, and group B swing door with cartilage graft. Concealment will be carried out using pocket concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient will be blind about the group of intervention. Due to the finding assessment will be performed after surgery and the method applied is not detectable after surgery hence outcome assessor is automatically blinded regarding the group of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Arak University of Medical Sciences

Street address

Research and Technology Deputy of Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.ARAKMU.REC.1400.045

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

Deviated nasal septum

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

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

Nasal septum deviation

Timepoint

1 month after surgery

Method of measurement

Vertical perpendicular line on line connecting pupils

2**Description**

Patient's satisfaction

Timepoint

1 month after surgery

Method of measurement

visual analogue scale (VAS)

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

Not applicable

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Intervention group: The surgical procedure performed under general anesthesia and one or more batten grafts made of septal cartilage is interposed between the cut

ends of the caudal L-strut and then sutured. After surgery medications and follow-up are the same in both groups and are those routinely conducted in septoplasty.

Category

Treatment - Surgery

2**Description**

Control group: The surgical procedure performed under general anesthesia and deviated septum is interposed only using swing door technique without graft. After surgery medications and follow-up are the same in both groups and are those routinely conducted in septoplasty.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dey Limited Surgery Center

Full name of responsible person

Mehdi Heidarizade

Street address

In front of the Department of Transfusion Medicine, Pharmacy upper floor Bu Ali, Street Shahid Shiroodi (Khoram), Arak, Iran.

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Web page address

<http://www.deylimitedsurgerycenter.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Mehdi Heidarizade

Position

Assistant Professor of OMFS

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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