Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 conducted on totally 40 patients in two groups of intervention and control using block randomization and double blinded methods. Concealment will carried out using pocket concealment.

Settings and conduct
The study will 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 f 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 Heidarizade

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Country
Iran (Islamic Republic of)

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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 carried out using pocket concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient will blind about the group of intervention. Due to the finding assessment will performed after surgery and the method applied is not detectable after surgery hence outcome assessor is automatically blinded regarding the group f 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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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