

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Heidarizade

##### 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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info@dscs.ir

**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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info@arakmu.ac.ir

**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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**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mehdi Heidarizade

**Position**

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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