Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of results following septorhinoplasty with modified swing door (before and after clinical trial)

Protocol summary

Study aim
To determine the results of septo-rhinoplasty treatment using the modified swing door technique

Design
Clinical trial without control group, without randomization and as a before and after trial

Settings and conduct
In this study, all rhinoplasty surgeries are performed under general anesthesia and the open surgical technique is used for better access to the septum. Septoplasty is performed with the introduced technique. After the tip plasty, osteotomy is performed externally. An intranasal splint is used for one week. Extranasal splint remains in the area for one week. Three months after the surgery, photographs are taken of the patients.

Participants/Inclusion and exclusion criteria
The inclusion criteria for this study include adult patients over 18 years of age with nasal deformity and deviation in the septum who are applying for rhinoplasty, who are not suffering from cancer, do not have diabetes, cardiovascular problems, and immune system deficiency. Patients with a history of previous rhinoplasty are excluded from the study.

Intervention groups
First, photographs are taken of the patients before the operation. Septoplasty is performed by a surgeon with a new method on patients. An intranasal splint is used for one week. Extranasal splint remains in the area for one week. Three months after the surgery, photographs are taken of the patients. The results are reported using three MiRa tools, ROE ranking and anthropometric evaluation.

Main outcome variables
The level of patient satisfaction with the MiRa tool, ROE rating and anthropometric evaluation on post-operative photography within 3 months of rhinoplasty surgery is measured.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230812059129N1**
Registration date: **2023-10-02, 1402/07/10**
Registration timing: **retrospective**

Last update: **2023-10-02, 1402/07/10**
Update count: **0**

Registration date
2023-10-02, 1402/07/10

Registrant information

Name
Mehdi Heidarizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-20, 1402/05/29

Expected recruitment end date
2023-09-20, 1402/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of results following septorhinoplasty with modified swing door (before and after clinical trial)

Public title
comparison of results following septorhinoplasty with modified swing door (before and after clinical trial)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients over 18 years old Suffering from nasal deformity and deviation in the septum Rhinoplasty applicant No cancer The absence of diabetes, cardiovascular problems and immune system defects
Exclusion criteria:
History of previous rhinoplasty
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Sardasht
City
Arak
Province
Markazi
Postal code
٣٨١٩٦٩٣٣٤٥
Approval date
2023-07-04, 1402/04/13
Ethics committee reference number
IR.ARAKMU.REC.1402.102

Health conditions studied

1

Description of health condition studied
nasal septal deviation
ICD-10 code
J34.2
ICD-10 code description
Deviated nasal septum

Primary outcomes

1

Description
Objective comparison of angles with deviation of anthropometric parameters
Timepoint
3-months after surgery
Method of measurement
Face photographs

2

Description
Evaluation of nasal deformity before and after septorhinoplasty
Timepoint
3-months after surgery
Method of measurement
MiRa standard scale

3

Description
Evaluation of patient satisfaction after septorhinoplasty
Timepoint
3-months after surgery
Method of measurement
Rhinoplasty Outcome Evaluation (ROE) scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, photographs are taken of the patients before the operation. Septoplasty is performed by a surgeon on patients with a new method. In this technique, all rhinoplasty surgeries are performed under general anesthesia and open surgery technique is used for better access to the septum. The skin flap of the dorsum of the nose is raised. In the midline, the middle and medial domes and coruras as well as the upper lateral cartilages are separated from the septum and an excellent access to the septum is achieved. Submucoperichondral flaps are raised bilaterally. In

patients with cartilaginous or bony hump, the bony hump is removed with the help of a rasp and the cartilaginous hump is removed with a No. 15 blade. l-strut is prepared with a No. 15 blade so that its caudal edge is at a distance of ten mm from the caudal edge of the septum and its lateral edge is at a distance of 20 mm from the lateral edge of the septum. The cartilaginous clamp is harvested from the caudal part of the dorsal incision and in the vicinity of the bony septum. Then, an incision is made parallel to the transverse surface of the septum and at a distance of 10 mm from it, from the caudal septum (Heidarizadeh incision), which determines the length of this incision, the location and the amount of deviation of the septum. The cartilage clamp harvested in the previous stage is placed vertically between the two horizontal parts created as a result of Heidarizadeh incision, without any additional maneuvers, and separates the two parts of the septum in the area of the tip of the nose like a wedge. The cephalocaudal position of this grip is also dependent on the severity of the deviation and the amount of correction required. For the plastic type, after cephalic resection, transdome and interdome sutures are applied; The columellar strut is placed, and then a 2mm thick and 7mm wide cap is placed in the area of the dome (the distance between the tip defining points). Finally, diced cartilage is placed and osteotomy is performed externally. If needed, alarplasty is performed in the usual way by resection of a wedge-like area and the area is sutured with 0-6 nylon thread. An intranasal splint is used for one week. Extranasal splint remains in the area for one week. Three months after the surgery, photographs are taken of the patients.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dey limited surgery center

Full name of responsible person

Mehdi Heidarizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak 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

-

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 Heidarizadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Oral and maxillofacial surgery

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Person responsible for scientific inquiries

Contact

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Assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of analyzes and data of each patient are accessible

When the data will become available and for how long

A year after the publication of the article

To whom data/document is available

Academic researchers and reviewers of medical journals

Under which criteria data/document could be used

Any analysis on the data of each patient is allowed, but it should be done by referees of medical journals

From where data/document is obtainable

The author and journal published the article

What processes are involved for a request to access data/document

The email will be given to the author or the publishing journal and the information will be sent shortly.

Comments