

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between doing and not doing spreader(graft or flap) in rhinoplasty patients with hump more than 3mm with respect to aesthetic and respiratory issues

Protocol summary

Study aim

Comparison between doing and not doing spreader (graft or flap) in rhinoplasty patients with a hump of more than 3 mm in terms of beauty and respiration

Design

A clinical trial with the control group, double-blind, randomized, on 60 patients

Settings and conduct

The present study is about comparison between doing and not doing spreader (graft or flap) in rhinoplasty patients with a hump of more than 3 mm in terms of beauty and respiration. This study is performed in the plastic surgery department of Taleghani Hospital in Ahvaz. The study is a double-blind clinical trial. Patients and the evaluator of the study outcome are blinded to the grouping of patients.

Participants/Inclusion and exclusion criteria

Rhinoplasty patients who do not have clinical problems to enter the study. Full patient consent is required to enter the study.

Intervention groups

In the first intervention group, rhinoplasty is performed by spreader graft method and in the second intervention group, surgery is performed by spreader flap method.

Main outcome variables

Mean score of rhinomanometric test indices; frequency distribution of patients' satisfaction in terms of aesthetics; frequency distribution of patients' satisfaction in terms of respiratory function; frequency distribution of nasal congestion and its severity (mild, moderate, severe) based on examination; frequency distribution of presence or absence Cottle sign

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201109049320N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

roozbeh rahbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8571

Email address

rahbar-r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

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

Comparison between doing and not doing spreader(graft or flap) in rhinoplasty patients with hump more than

3mm with respect to aesthetic and respiratory issues

Public title
The effect of spreader on the aesthetic and respiratory issues of rhinoplasty patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Absence of clinical problems for the patient Patient consent to participate in the study
Exclusion criteria:
Existence of structural problems such as: nasal obstruction and a history of deformity that requires rhinoplasty.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, eligible patients are divided into group undergoing rhinoplasty by spreader graft method and the group undergoing surgery by spreader flap method and the group of control patients. Samples are included in this study by the simple randomization method. To group patients in a simple random way, the letters A, B and C are written on 60 pieces of paper with equal dimensions (each letter is written on 20 pieces of paper). After entering, each patient selects one of the papers with an equal chance and thus the patient group is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is not informed that he or she is in the control or sample group. The specialist who performs rhinomanometric tests on patients before and after surgery is unaware of those in the control or sample group. The evaluator who evaluates the results of the study is unaware of the people in the control or sample group. The person analyzing the study data is unaware of the people in the control or sample group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ethics Committee, Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

61877954386

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.071

Health conditions studied

1

Description of health condition studied

Rhinoplasty patients with a hump greater than 3 mm

ICD-10 code

J34.8

ICD-10 code description

Other specified disorders of nose and nasal sinuses

Primary outcomes

1

Description

Nasal congestion

Timepoint

Before and after surgery

Method of measurement

Breathing quality score

Secondary outcomes

1

Description

Severe deviation of the nasal septum

Timepoint

Before and after surgery

Method of measurement

clinical examination

2

Description

The presence or absence of shortness of breath

Timepoint

Before and after surgery

Method of measurement

Clinical examination

3

Description

Right nasal resistance

Timepoint

Before and after surgery

Method of measurement

Rhinoomanometry test by active anterior rhinomanometry according to the protocol of the International Committee for Standardization

4

Description

Left nasal resistance

Timepoint

Before and after surgery

Method of measurement

Rhinoomanometry test by active anterior rhinomanometry according to the protocol of the International Committee for Standardization

5

Description

Total resistance

Timepoint

Before and after surgery

Method of measurement

Rhinoomanometry test by active anterior rhinomanometry according to the protocol of the International Committee for Standardization

6

Description

Right nasal airflow

Timepoint

Before and after surgery

Method of measurement

Rhinoomanometry test by active anterior rhinomanometry according to the protocol of the International Committee for Standardization

7

Description

Left nasal airflow

Timepoint

Before and after surgery

Method of measurement

Rhinoomanometry test by active anterior rhinomanometry according to the protocol of the International Committee for Standardization

8

Description

Total air flow (units: Pascals per milliliter per second)

Timepoint

Before and after surgery

Method of measurement

Rhinoomanometry test by active anterior rhinomanometry according to the protocol of the International Committee for Standardization

Intervention groups

1

Description

Intervention group: Spreader (graft or flap) in rhinoplasty patients with a hump of more than 3 mm

Category

Treatment - Surgery

2

Description

Control group: Do not do a spreader (graft or flap) in rhinoplasty patients with a hump larger than 3 mm

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Taleghani Hospital

Full name of responsible person

Roosbeh Rahbar

Street address

Plastic surgery department, Taleghani hospital, Padadshahr

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Ahvaz

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61877954386

Phone

+98 61 3554 0254

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rahbar-r@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

Street address

Vice Chancellor for Research, Ahvaz Jundishapur university of medical sciences, Golestan Blvd.

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Roosbeh Rahbar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Plastic Surgery

Street address

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available