Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the functional effect of spreader graft versus autospreader flap in rhinoplasty using rhinomanometry

Protocol summary

Study aim
Effect of spreader graft and autospreader flap in rhinoplasty using rhinomanometry

Design
Nasal airway flow will be measured in fifty patients with relatively similar aesthetic conditions before surgery, using rhinomanometry. Patients are randomly divided into two equal groups using a random number table, half of them will receive the spreader graft and the others will receive the autospreader flap. subjects will be fallowed three monthes post operation using same rhinomanometry

Settings and conduct
Rhinomonometry test was performed for all the patients. Cases were divided into two groups: Spreader graft group or group A And Autospreader flap group or group B and each patient would be refereed to the surgeon having one of A or B Cards in hand and the surgeon will proceed as indicated. 3 months post operation rhinomonometry test will be performed again and the results will be analyzed

Participants/Inclusion and exclusion criteria
Participants should be at the desired age range and sex and should not have a history of nose trauma and nasal surgery.

Intervention groups
Rhinoplasty using autospreader flap and spreader graft

Main outcome variables
Change in airflow after rhinoplasty in both techniques

General information

Reason for update

Acronym
none

IRCT registration information
IRCT registration number: **IRCT20170711035014N2**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **retrospective**
Last update: **2018-06-06, 1397/03/16**
Update count: **0**

Registration date
2018-06-06, 1397/03/16

Registrant information

Name
assila vaezi

Name of organization / entity
dental faculty

Country
Iran (Islamic Republic of)

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+98 51 3893 8245

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vaezia941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source
Mashhad University of Medical Sciences Research Center

Expected recruitment start date
2016-12-21, 1395/10/01

Expected recruitment end date
2017-12-22, 1396/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the functional effect of spreader graft versus autospreader flap in rhinoplasty using rhinomanometry

Public title
Comparison of outcomes of two types of spreader graft versus autospreader flap in rhinoplasty using rhinomanometry

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: aesthetic problems; breathing problems.
Exclusion criteria:
Exclusion criteria: lack of cooperation after surgery; revision surgery; no need to apply the spreader during operation.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
25 cards indicating A letter and 25 cards indicating B Letter were randomly chosen by patients: Spreader graft group or group A And Autospreader flap group or group B and each patient would be refereed to the surgeon having one of A or B Cards in hand and the surgeon will proceed as indicated
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the researcher and analyzer are unaware of the chosen card and the patient is unaware of the procedure
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2015-12-14, 1394/09/23
Ethics committee reference number
IR.MUMS.SD.REC.1394.239

Health conditions studied

1

Description of health condition studied
Nasal functional problems
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nasal flow change during inhale/exhale in both cavities
Timepoint
Before operation and thirty days post operation
Method of measurement
Rhinomanometry

Secondary outcomes

1

Description
Aesthetic outcomes and changes of graft application in Tip elevation and tip rotation in both procedures
Timepoint
Not included in the study
Method of measurement
Not included in the study

Intervention groups

1

Description
Group1: Patients having surgery using autospreader flap.
Category
Treatment - Surgery

2

Description
Group 2: patients having surgery using spreader graft.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital
Full name of responsible person
Mahdi Gholami
Street address
Ahmad abad Ave., Mashhad Town,
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9176699199
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Administration Center(Qoreishi Building), Daneshgah St.
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9919191778
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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
Mashhad 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
Mashhad Dental faculty
Full name of responsible person
Assila Vaezi
Position
OMFS Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Position
OMFS Resident
Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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

Due to the large number of participants and the study of rhinomanometry in the form of charts and tables requiring expert examination, there is no need to publish the results.

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Airflow and air resistant totally and in right and left nostril

When the data will become available and for how long

One year

To whom data/document is available

Academic responsible

Under which criteria data/document could be used

In cases of statistics analysis and standardization of study circumstances

From where data/document is obtainable

Researcher

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

Rhinomanometry before and 3 month after rhinoplasty

Comments