

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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 followed three months post operation using same rhinomanometry

Settings and conduct

Rhinomanometry 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 referred to the surgeon having one of A or B Cards in hand and the surgeon will proceed as indicated. 3 months post operation rhinomanometry 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)

Phone

+98 51 3893 8245

Email address

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,

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0000

Email

Quaem.Medical.Center@mums.ac

Mashhad Dental faculty

Full name of responsible person

Assila Vaezi

Position

OMFS Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

no. 99, 13th Daneshjoo St.

City

Mashhad

Province

South Khorasan

Postal code

9188976391

Phone

+98 51 3893 8245

Fax**Email**

assilavz@gmail.com

Web page address**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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9919191778

Phone

+98 51 3841 3007

Email

assilavz@gmail.com

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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Gholami

Position

OMF Surgeon

Latest degree

Specialist

Other areas of specialty/work**Street address**

Surgical department of Mashhad Dental Faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3893 8245

Fax**Email**

gholami42143@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Dental Faculty

Full name of responsible person

Assila Vaezi

Position

OMFS Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

No. 99, 13th Daneshjoo St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9188976391

Phone

+98 51 3893 8245

Fax

Email

assilavz@gmail.com

Web page address

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