

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of effect of spreader graft in aesthetic of nasal dorsum after primary rhinoplasty; A randomized double blind clinical trials.

Protocol summary

Summary

The aim of the present study is to evaluate the effect of spreader graft in aesthetic of nasal dorsum after primary rhinoplasty. This study is randomized, double blind, with control, single center, phase-2 of clinical trial. Blinding is done for patients and researcher who measures the outcomes. The main inclusion criterion is: The patient must be in ASA CL 1 classification and with no contraindication for nasal surgery. The main exclusion criteria are history of trauma before and after surgical procedure, nasal asymmetry, dorsal hump reduction more than 3 mm, presence of hypertrophic turbinate, consumption of drugs which intervene blood coagulation. Target sample size is 20 patients. In intervention group spreader graft is placed and in control group is not placed. The time of this study is 6 months. Primary outcome is placing spreader graft.

General information

Acronym

:

IRCT registration information

IRCT registration number: **IRCT201702049926N5**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

Mohammad Reza Jamalpour

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-chancellors of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-05-08, 1396/02/18

Expected recruitment end date

2017-11-08, 1396/08/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of spreader graft in aesthetic of nasal dorsum after primary rhinoplasty; A randomized double blind clinical trials.

Public title

Effect of spreader graft on aesthetic of nose

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion and Exclusion criteria: (Inclusion criteria: Should be in American Society Of Anesthesiologist CI I classification; No contraindication for nose surgery
Exclusion criteria; Hx of trauma before and after surgical procedure; Nasal asymmetry; Respiratory problem; Nasal dorsal hump reduction more than 3 mm; Presence of scar on nasal skin; Presence of hypertrophic turbinate; Presence of concha bllusa; consumption of drugs which intervene blood coagulation)

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Hamadan University of Medical Sciences

Street address

no.16, Hamadan University of Medical Sciences

City

Hamadan

Postal code**Approval date**

2017-01-28, 1395/11/09

Ethics committee reference number

IR.umsha.REC.1395.480

Health conditions studied**1****Description of health condition studied**

Nasal deformity

ICD-10 code

Q30

ICD-10 code description

Congenital malformation of nose

Primary outcomes**1****Description**

Aesthetic of nasal dorsum

Timepoint

6 months

Method of measurement

Observation

Secondary outcomes**1****Description**

Satisfaction of patient

Timepoint

6 month

Method of measurement

Questionnaire

2**Description**

Asymmetry of dorsum

Timepoint

6 month

Method of measurement

Assessment of surgeon

3**Description**

Depression of dorsum

Timepoint

6 month

Method of measurement

Assessment of surgeon

4**Description**

Wideness of dorsum

Timepoint

6 month

Method of measurement

Assessment of surgeon

5**Description**

Step

Timepoint

6 month

Method of measurement

Assessment of surgeon

Intervention groups**1****Description**

Placing spreader graft

Category

Treatment - Surgery

2

Description

Spreader graft is not placed

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr Mohammadresa Jamalpour

Street address

No 20, Mazdaghine Street, Shahid Beheshti Street

City

hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellors of Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Maryam Askarinia

Street address

No.14, Vice-chancellors of Research and
Technology, Hamadan University of Medical Sciences

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellors of Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Jamalpour

Position

Associated professor of Oral and Maxillofacial Surgery

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty