

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between absorption rate of Acellular Dermis and homograft Fascia Lata for prevention of dorsal irregularities in primary rhinoplasty patients

Protocol summary

Summary

The aim of this study is to compare of Acellular Dermis and homograft Fascia Lata for nasal dorsal irregularities prevention. Inclusion criteria: the thin skin patients; 19 to 55 years old; with a dorsal nasal hump; without modification of radix. Exclusion criteria: previous rhinoplasty surgery; history of nasal trauma and nasal fracture; diabetic mellitus; immunologic disease; vascular and hemorrhagic diseases. 68 patients with these inclusion and exclusion criteria for primary open rhinoplasty are enrolled. After a standard rhinoplasty procedure, a layer of Acellular Dermis with 0.6-0.9 mm thickness and 20 x 40 mm in dimension is placed in the pocket of the dorsum. This study is performed in the private Markazi Clinic in Tehran from March 2013 and 2015. To assess the absorption rate of these two products as the primary outcome of the study, dorsal height is measured on right lateral photographs, 6 and 12 months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041717312N1**

Registration date: **2015-05-12, 1394/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-12, 1394/02/22

Registrant information

Name

Roghayeh Hamidian

Name of organization / entity

Rasul Akram Hospital

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Kish Hamanandsazbaft Company

Expected recruitment start date

2013-03-04, 1391/12/14

Expected recruitment end date

2015-03-05, 1393/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between absorption rate of Acellular Dermis and homograft Fascia Lata for prevention of dorsal irregularities in primary rhinoplasty patients

Public title

Prevention of nasal skin irregularity after rhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The thin skin patients; 19 to 55 years old; with a dorsal nasal hump; without modification of radix. Exclusion criteria: previous rhinoplasty surgery; history of nasal trauma and nasal fracture; diabetic mellitus; immunologic disease; vascular and hemorrhagic diseases.

Age

From **19 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

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

Iran University of Medical Sciences

Street address

Ethics Committee, School of Medicine, Iran University of Medical Sciences, next to Milad Hospital, Hemat Highway

City

Tehran

Postal code

Approval date

2015-01-11, 1393/10/21

Ethics committee reference number

93/d/105/4844

Health conditions studied

1

Description of health condition studied

Follow-up care involving plastic surgery of open rhinoplasty

ICD-10 code

Z42.0

ICD-10 code description

Follow-up care involving plastic surgery of head and neck

Primary outcomes

1

Description

Acellular Dermis absorption rate

Timepoint

6 and 12 months after surgery

Method of measurement

Dorsal height is measured by using computer software Teb Negar Cosmetic Simusurge on right lateral photographs

2

Description

Homograft Fascia Lata absorption rate

Timepoint

6 and 12 months after surgery

Method of measurement

Dorsal height is measured by using computer software Teb Negar Cosmetic Simusurge on right lateral photographs

Secondary outcomes

1

Description

Infection

Timepoint

3 and 6 and 12 months after surgery

Method of measurement

Physical examination

2

Description

Dorsal irregularity

Timepoint

12 months after surgery

Method of measurement

Physical examination

3

Description

Migration of product

Timepoint

3 and 6 and 12 months after surgery

Method of measurement

Physical examination

4

Description

Extrusion of product

Timepoint

3 and 6 and 12 months after surgery

Method of measurement

Physical examination

5

Description

Seroma formation
Timepoint
3 and 6 and 12 months after surgery
Method of measurement
Physical examination

Intervention groups

1

Description

At the end of standard rhinoplasty procedure, a layer of Acellular Dermis with 0.6-0.9 mm thickness and 20 x 40 mm in dimension is placed in the pocket of the dorsum.

Category

Treatment - Surgery

2

Description

At the end of standard rhinoplasty procedure, a layer of homograft Fascia Lata with 0.9-0.6 mm thickness and 20 x 40 mm in dimension is placed in the pocket of the dorsum.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Markazi Clinic

Full name of responsible person

Dr Aliresa Mohebbi

Street address

No.29, Markazi Clinic, Valinejad Ave, Valiasr St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kish Hamanandsazbaft Company

Full name of responsible person

Saba Hariri

Street address

No.8, Eastern 19th Ave, Sarafha St, Saadat Abad

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kish Hamanandsazbaft Company

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

Rasul Akram Hospital

Full name of responsible person

Dr Roghayeh Hamidian

Position

Resident of Otolaryngology Head and Neck surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasul Akram Hospital

Full name of responsible person

Dr Aliraza Mohebbi

Position

Assistant professor of Otolaryngology Head and Neck surgery

Other areas of specialty/work

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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