

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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

+98 21 6651 1011

###### Email address

armohebbi@tums.ac.ir

###### 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 Alireza 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**

**Street address**

Department of Otolaryngology Head and Neck surgery, Rasul Akram Hospital, Niayesh Ave, Saterkhan St

**City**

Tehran

**Postal code**

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+98 21 6651 1011

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**Web page address**

**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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## Person responsible for updating data

### 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****Street address**

Department of Otolaryngology Head and Neck surgery, Rasul Akram Hospital, Niayesh Ave, Satarkhan St

**City**

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**Postal code****Phone**

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**Fax****Email**

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**Web page address**

## 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*