# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison of columella scar between nylon thread and vicryl thread in rhinoplasty

### Protocol summary

**Study aim**
Comparison of the effect of vicryl thread with nylon thread with a diameter of 0.6 on the scar of the nasal columella after rhinoplasty surgery.

**Design**
This study was designed as a prospective, randomized, double-blind, parallel-group clinical trial. A total of 56 patients were enrolled and randomly allocated to two equal groups of 28 participants each. The control group underwent columellar incision closure using a permanent non-absorbable suture (6-0 Nylon), while the intervention group received closure with a non-rapid absorbable suture (6-0 Vicryl).

**Settings and conduct**
The clinical trial study aims to compare the effect of Vicryl sutures with nylon sutures on columellar scarring after rhinoplasty in patients visiting Amir Alam Hospital in Tehran in the year 1403 (2024-2025).

**Participants/Inclusion and exclusion criteria**
All patients over the age of 18 who undergo primary open rhinoplasty for any reason other than nasal reconstruction related to cancer removal and are able to provide informed consent will be included in the study. Patients with a history of previous nasal surgery who do not have an incision on the columella will also be included. Patients with previous surgery that involves a columellar incision and patients with a known history of skin disorders affecting scarring will be excluded from the study. Additionally, patients with missing data or loss to follow-up will also be excluded from the study. Criteria for exclusion include being under 18 years old, a history of skin disease, and previous nasal surgery history.

**Intervention groups**
The control group will have the columellar incision closed with a permanent non-absorbable suture (6-0 nylon) and the intervention group will have the incision closed with an absorbable suture (6-0 non-rapid vicryl).

**Main outcome variables**
Age؛ Gender؛ Group؛ Time؛ SBES score؛ PSAQ score and subscales

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250129064567N1**
Registration date: **2026-04-11, 1405/01/22**
Registration timing: **retrospective**

Last update: **2026-04-11, 1405/01/22**
Update count: **0**

**Registration date**
2026-04-11, 1405/01/22

**Registrant information**

**Name**
Sadegh Aliheydari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-04-19, 1404/01/30

**Expected recruitment end date**
2026-04-18, 1405/01/29

**Actual recruitment start date**
2025-03-21, 1404/01/01

**Actual recruitment end date**
2026-03-21, 1405/01/01

**Trial completion date**

2026-04-04, 1405/01/15

**Scientific title**
Comparison of columella scar between nylon thread and vicryl thread in rhinoplasty

**Public title**
Comparison of sutures in the front of the nose between nylon thread and vicryl thread in nose surgery

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
All patients over the age of 18 who have undergone primary open rhinoplasty for any reason other than nasal reconstruction related to cancer removal and are able to give informed consent. Patients with a history of previous nose surgery who do not have an incision on the columella will also be included

**Exclusion criteria:**
Patients with previous surgery involving a columellar incision and patients with a known history of skin disorders affecting scarring. Patients with missing information or patient loss in follow-up Patients under 18 years old

**Age**
From **18 years** old

**Gender**
Both

**Phase**
0

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **56**
Actual sample size reached: **56**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, simple randomization was employed. In this approach, each eligible patient had an equal probability of being assigned to either the intervention group (Vicryl) or the control group (Nylon). The allocation for each patient was performed independently and without considering the number of participants already assigned to each group. This process ensures that the group assignment is completely unpredictable and free from selection bias. Both the surgical team and the researchers were blinded to the group allocation prior to the operation (allocation concealment). The type of suture material used for each patient became known only after the procedure. One characteristic of simple randomization is that, although the probability of assignment is equal for both groups, the final number of patients in each group may not be exactly the same. This slight imbalance is more common in studies with smaller sample sizes and is considered a normal feature of this method. The use of simple randomization reduces selection bias, increases the internal validity of the study, and provides a fair basis for comparing outcomes between the two groups.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Tehran University of Medical Sciences, Amira Alam Hospital

**Street address**
Amir Alam Hospital, Saadi Northern Street, Darvaze Dolat, Ferdowsi Square

**City**
tehran

**Province**
Tehran

**Postal code**
1145765111

**Approval date**
2024-08-20, 1403/05/30

**Ethics committee reference number**
IR.TUMS.AMIRALAM.REC.1403.025

## Health conditions studied

**1**

**Description of health condition studied**
Comparison of columella scars between nylon and vicryl sutures in rhinoplasty

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Appearance (color match, hypo- and hyperpigmentation, redness, length, width, smoothness, shine, bumps, and texture), symptoms (itching, pain, discomfort, numbness, etc.) Columella location

**Timepoint**
6 and 12 months after surgery

**Method of measurement**
Stony Brook Assessment Scale (SBES) and Patient Assessment Questionnaire (PSAQ)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: The control group included closure of the columellar incision with a permanent nonabsorbable suture (6-0 nylon).
**Category**
Treatment - Surgery

### 2

**Description**
Intervention group: The intervention group will be closed with an absorbable suture (6-0 Vicryl non-rapid).
**Category**
Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Amiralam Hospital
**Full name of responsible person**
Behrooz Shaternia
**Street address**
Amir Alam Hospital., Saadi Northern Street., Darvaze Dolat., Ferdowsi Square
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## Sponsors / Funding sources

### 1

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Tehran University of Medical Sciences
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**Email**
Hamiralam@sina.tums.ac.ir
**Web page address**
https://amiralam.tums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tehran 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**
Tehran University of Medical Sciences
**Full name of responsible person**
Sadegh Aliheydari
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Ear, Nose, and Throat
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## Person responsible for scientific inquiries

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**Latest degree**
Medical doctor

**Other areas of specialty/work**
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## Person responsible for updating data

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**Full name of responsible person**
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**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**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**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Information obtained from data summarization is given.

**When the data will become available and for how long**
After finishing the article and concluding

**To whom data/document is available**
Everyone

**Under which criteria data/document could be used**
In order to complete the article correctly

**From where data/document is obtainable**
Tehran University of Medical Sciences, Amir A'lam Hospital 0216672706064 with Ms. Alipour, Head of Hospital Education 09037900972 Dr. Sadegh Aliheydari via SMS Email sadegh.aliheydari1991@gmail.com Dr. Sadegh Aliheydari's postal code: 4561638461

**What processes are involved for a request to access data/document**
Written request and reason for it

**Comments**