

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between Nylon and PDS suture for development and maintenance of rotation and projection in Tongue-in-groove technique rhinoplasty on rhinoplasty patients

Protocol summary

Study aim

Determine difference between Nylon vs PDS Suture in Tongue-In-Groove technique in development and maintenance of nasal tip projection and rotation in Rhinoplasty

Design

In this block-randomized double-blind clinical trial, 64 randomly-selected patients were randomized to receive PDS (n=22) or nylon (n=29) suture material (both 0-5) in tongue in groove technique. The blocks were developed by epidemiologist with one code for each patient was considered to assign in A or B group. It was only known by epidemiologist and the surgeon was blind till TIG operation and also patients and minor researchers were blind

Settings and conduct

The standard image before and after (in months 1, 6, and 12) was prepared and the projection and rotation was determined by Photoshop software via Goode's method and nasolabial angle was measured. The satisfaction rate from rhinoplasty procedure was determined by Visual analogue scale (VAS) in 1, 6, and 12 months after. The nasal function was measured by Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS) scale before and 1 year after surgery. The skin thickness and septal deviation were recorded by preoperative physical examination and also the remained lateral crura were measured by caliper

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who were enrolled for External incision Rhinoplasty and Tongue in Groove technique was possible to Exclusion Criteria: congenital anomalies; severe septal deviation; severe nasal bone deviation; hypersensitivity to suture materials; revision surgery

Intervention groups

Intervention group 1: using Nylon 5-0 Suture in TIG

Technique Intervention group 2: using PDS 5-0 Suture in TIG Technique

Main outcome variables

Nasal Tip Projection; Nasal Tip Rotation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080820001056N4**

Registration date: **2020-03-12, 1398/12/22**

Registration timing: **retrospective**

Last update: **2020-03-12, 1398/12/22**

Update count: **0**

Registration date

2020-03-12, 1398/12/22

Registrant information

Name

babak saedi

Name of organization / entity

tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 2270 0765

Email address

saedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-02, 1396/07/10

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

2017-10-02, 1396/07/10

Actual recruitment end date

2018-02-04, 1396/11/15

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Comparison between Nylon and PDS suture for development and maintenance of rotation and projection in Tongue-in-groove technique rhinoplasty on rhinoplasty patients

Public title

comparison between Nylon versus PDS in Tongue-in-groove technique in rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients enrolled in open rhinoplasty and it was possible to perform TIG

Exclusion criteria:

congenital anomalies severe septal deviation severe nasal bone deviation hypersensitivity to material used in surgery revision surgery

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **64**

Actual sample size reached: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

with block randomization of size 4, the patients were placed in 2 groups of A and B. In one group Nylon suture and in other group PDS suture was used. The blocks were developed by epidemiologist with one code for each patient was considered to assign in A or B group

Blinding (investigator's opinion)

Double blinded

Blinding description

The epidemiologist was the only person who knows randomization code. The surgeon will not know about the suture material types until the end of surgery. The surgeon assistant will let him know suture material types at the end of surgery during TIG. The surgeon assistant will be blinded about suture material before surgery and patients won't know suture materials were used during their surgeries.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethics committee of Tehran University of Medical Sciences

Street address

No 1068, First Entrance, Block 5, Ekbatan town

City

tehran

Province

Tehran

Postal code

1396843193

Approval date

2017-09-26, 1396/07/04

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3571

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

Rhinoplasty

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Nasal tip projection

Timepoint

Nasal tip projection measurements before intervention and 1, 6, 12 months after intervention

Method of measurement

Goode's ratio

2**Description**

Nasal tip rotation

Timepoint

Nasal tip rotation measurements before intervention and 1, 6, 12 months after intervention

Method of measurement

nasolabial angle

Secondary outcomes

1

Description

Patient's Satisfaction of Rhinoplasty

Timepoint

1,6,and 12 months after surgery

Method of measurement

Visual Analogue Scale(VAS)

2

Description

Nasal Function

Timepoint

Before and 1 year after surgery

Method of measurement

Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS) scale

Intervention groups

1

Description

Intervention group 1: using Nylon 5-0 Suture(ethicon company) in TIG Technique. only one suture was used.Nasal tip projection measurements by Goode's ratio method and Nasal tip rotation measurements by nasolabial angel is done before intervention visit and 1,6,12 months after intervention visit by performing standard photography and photo analysis with photoshop .also checking the Patient's Satisfaction of Rhinoplasty by Visual Analogue Scale in visits of 1,6,12 months after intervention and checking nasal function before intervention visit and 12 months after intervention visit with SCHNOS

Category

Treatment - Surgery

2

Description

Intervention group: 2 ,using PDS 5-0 Suture(ethicon company). in TIG Technique.only one suture was used.Nasal tip projection measurements by Goode's ratio method and Nasal tip rotation measurements by nasolabial angel is done before intervention visit and 1,6,12 months after intervention visit by performing standard photography and photo analysis with photoshop .also checking the Patient's Satisfaction of Rhinoplasty by Visual Analogue Scale in visits of 1,6,12 months after intervention and checking nasal function before intervention visit and 12 months after intervention visit with SCHNOS

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Babak Saedi

Street address

Keshavarz Blvd Ghods avenu Tehran University

City

Tehran

Province

Tehran

Postal code

141979733141

Phone

+98 21 6658 1628

Email

saedi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Sahrain

Street address

Vice Chancellor for Research,Centarl Office of Tehran University of Medical Science,Qods ave,Keshavarz blv

City

tehran

Province

Tehran

Postal code

141979733141

Phone

+98 21 8163 3619

Email

rmo@tums.ac.ir

Grant name

Vice Chancellor for Research Tehran University of Medical sciences

Grant code / Reference number

9411369010

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

Babak Saedi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Keshavars BLV ,Imama khomainee hospital

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 2270 0765

Fax

+98 21 6658 1628

Email

saedi@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Babak saedi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Keshavars BLV ,Imam khomainee Hospital

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 2270 0765

Fax

+98 21 6658 1628

Email

saedi@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahand Kia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

No 1068,First Enterance,Block 5,Ekbatan city

City

Tehran

Province

Tehran

Postal code

1396843193

Phone

+98 21 4469 4274

Email

kia.sahand@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

we will publish it in article

When the data will become available and for how long

we will publish it in article 2020

To whom data/document is available

nobody can have anything more than article

Under which criteria data/document could be used

we will publish it article but nobody can have access to other data

From where data/document is obtainable

we will publish it in article

What processes are involved for a request to access data/document

Contact with researchers

Comments