

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

To evaluate the effect of depressor septi muscle resection on projection and rotation of the nose in rhinoplasty patients with who have nasal drooping with laughter and comparison with control group: by tongue in groove technique; single blind randomized controlled trial

Protocol summary

Study aim

Determining the effect of depressor septi nasi resection on nasal projection and rotation in rhinoplasty patients who have drooping tip when smiling and compare it to the control group undergone tongue-in-groove technique

Design

A randomized trial with a control group, with parallel groups, single blind, randomized, on 37 patients in each group - Excel software rand function was used for randomization.

Settings and conduct

Patients who have referred to the Facial Plastic Surgery Clinic of Imam Khomeini Hospital and experience nasal drooping while laughing will be randomly divided into two groups. In the intervention group, the depressor septi muscle will be incised, but in the control group, it will remain intact. This study is single blind in that the evaluator of the research result and analyzer will be blinded.

Participants/Inclusion and exclusion criteria

All patients referred to the clinic enter the study during this period when they have referred to the clinic and are willing to participate in the study.

Intervention groups

In the control group: tongue in groove placed on the caudal septum or cartilage extension. In the intervention group: In addition to the intervention mentioned in the control group, the septum of the septum depressor muscle will be cut by sub-labial incision.

Main outcome variables

Projection rate; Rotation rate; Upper lip height; Upper lip position; Satisfaction with the result of the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080820001056N6**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **prospective**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

Registration date

2021-08-16, 1400/05/25

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

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effect of depressor septi muscle resection on projection and rotation of the nose in rhinoplasty patients with who have nasal drooping with laughter and comparison with control group: by tongue in groove technique; single blind randomized controlled trial

Public title

To assess the effect of depressor septi nasi resection on nasal projection in patients who have drooping tip when smiling

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients referred to the ENT clinic of Imam Khomeini Hospital

Exclusion criteria:

Previous rhinoplasty surgery
Congenital disease of the nose and lips
Dental or jaw problem
History of systemic disease
History of maxillary trauma
Surgery limited to the bony part of the nose
Injection of filler in the lips and nose

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with Block randomization method are grouped into quadruple blocks, designed by a statistical methodologist. The random assignment list is at the disposal of the supervisor and based on that, patients who have been given surgery and are satisfied with the surgery are divided into groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the need to make an additional incision under the lip in the intervention group, it is not possible to blind patients. The analysis of the photos and the relevant questionnaire is done by the ENT resident or the Facial Plastic Surgery Fellowship who does not know the type of intervention. Data collectors and those evaluating the outcome, as well as the Data Safety and Monitoring Committee and those drafting the article, are also blinded.

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

Central building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-07-18, 1400/04/27

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.155

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The degree of drooping of the nose when laughing

Timepoint

One year after the surgery

Method of measurement

Rate of nasal projection and rate on nasal rotation

Secondary outcomes

1

Description

Degree of patients' satisfaction

Timepoint

One year after surgery

Method of measurement

Visual Analogue Scale , SCHNOS(Standardized Cosmesis and Health Nasal Outcome Survey)

Intervention groups

1

Description

Intervention group: tongue in groove placed on the caudal septum, and then the septum of the septum depressor muscle will be cut by sub-labial incision.
Control group: tongue in groove technique on the caudal septum.

Category

Treatment - Surgery

2

Description

Control group: tongue in groove technique on the caudal septum.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Babak Saedi

Street address

Qarib St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Tehran University of Medical Sciences, Qods St.,
Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653911

Phone

+98 21 6405 3334

Email

tumspr@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

Shayad Dasdar

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Qarib St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Shayandasdar1374@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Babak Saedi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address
Qarib St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
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
Nika Kianfar
Position
Researcher
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Qarib St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000

Email
Shayandasdar1374@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

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

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Six months after publication

To whom data/document is available

Researchers

Under which criteria data/document could be used

Only for researching purposes

From where data/document is obtainable

Shayan Dasdar Email: shayandasdar1374@gmail.com

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

A written request from a valid place is required. Then, within 2 weeks the data will be provided.

Comments