

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparative study of the results of endoscopic sinus surgery and Concurrent Endoscopic Sinus Surgery and rhinoplasty with or without "Tongue In Groove" technique in patients undergoing Endoscopic Sinus Surgery

Protocol summary

Summary

Comparison of the results of endoscopic sinus surgery and Concurrent Endoscopic Sinus Surgery and Rhinoplasty with or without "Tongue In Groove" technique . This study is randomised, not blinded, without placebo, interventional and will done with 45 chronic rhinosinusitis patients undergoing rhinoplasty divided in 3 groups of 15 individuals. The first group will be treated by endoscopic sinus surgery alone. The second group will be treated by Concurrent Endoscopic Sinus Surgery and Rhinoplasty with "Tongue In Groove" technique and the third group will be treated by Concurrent Endoscopic Sinus Surgery and Rhinoplasty without "Tongue In Groove" technique. Inclusion criteria: CRS with or without nasal polyps; no Response to medical treatment; age 15 - 60 Exclusion criteria: Acute infection; Failure to complete medical treatment; immune system disorders; systemic disorders like hypertension, diabetes mellitus, chronic kidney disease and malignancy; pregnancy All three groups will undergo surgery. Patients before surgery and 1, 3 and 6 months after surgery will be evaluated in terms of the width of the middle meatus, edema of the nasal mucosa, Lund Kennedy score in endoscopy, patient satisfaction from the nose, surgeon satisfaction of the nose, difficulty breathing, nasal congestion. The intraoperative blood loss and the duration of surgery will be recorded. Recurrent nasal polyps in the examination 1, 3 and 6 months after surgery will be discussed. Finally, the data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051128006N1**

Registration date: **2017-07-13, 1396/04/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-13, 1396/04/22

Registrant information

Name

Mohamad Sadeghi

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the results of endoscopic sinus surgery and Concurrent Endoscopic Sinus Surgery and rhinoplasty with or without "Tongue In Groove" technique in patients undergoing Endoscopic Sinus Surgery

IR.TUMS.VCR.REC.1395.348

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis with or without polyposis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Edema of the nasal mucosa

Timepoint

One day before surgery and 1, 3 and 6 months after that

Method of measurement

Nasal Endoscopy

2

Description

The width of the middle meatus

Timepoint

One day before surgery and 1, 3 and 6 months after that

Method of measurement

Clinical examination and Nasal Endoscopy

3

Description

Endoscopic assessment of the nose

Timepoint

One day before surgery and 1, 3 and 6 months after that

Method of measurement

Nasal endoscopy by the Lund Kennedy scoring system

4

Description

Patient satisfaction from the nose

Timepoint

One day before surgery and 1, 3 and 6 months after that

Method of measurement

Questionnaire

5

Description

Surgeon satisfaction of the nose

Timepoint

One day before surgery and 1, 3 and 6 months after that

Method of measurement

Questionnaire

Public title

Comparing two surgical procedures for Sinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: CRS with or without nasal polyps; no Response to medical treatment; age 15 - 60 Exclusion criteria: Acute infection; Failure to complete medical treatment; immune system disorders; systemic disorders like hypertension, diabetes mellitus, chronic kidney disease and malignancy; pregnancy

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization for three interventional groups will done by balanced blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran/ Keshavarz s./ 16azar s./ Tehran university of medical sciences

City

Tehran

Postal code

Approval date

2016-07-24, 1395/05/03

Ethics committee reference number

6

Description

Difficulty breathing

Timepoint

One day before surgery and 1, 3 and 6 months after that

Method of measurement

Questionnaire

Secondary outcomes

1

Description

The duration of surgery

Timepoint

Intraoperative

Method of measurement

The report surgery

2

Description

Blood lost during surgery

Timepoint

Intraoperative

Method of measurement

Questionnaire

3

Description

Recurrent nasal polyps

Timepoint

1,3 and 6 months after surgery

Method of measurement

Nasal endoscopy

4

Description

Nasal congestion

Timepoint

One day before surgery and after that

Method of measurement

Questionnaire

Intervention groups

1

Description

Interventional group 1: Endoscopic sinus surgery alone

Category

Treatment - Surgery

2

Description

Intervention group 2: Endoscopic sinus surgery and rhinoplasty at the same time, with "Tongue In Groove" Technique

Category

Treatment - Surgery

3

Description

Intervention group 3: Endoscopic sinus surgery and rhinoplasty at the same time, without "Tongue In Groove" Technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital

Full name of responsible person

Fateme Tavakolnejad

Street address

ENT department, Emam Khomeini hospital, Keshavarz st, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Masud Yunesian

Street address

Office building of Tehran University of Medical Sciences, Keshavarz s., Tehran

City

Tehran

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, Vice chancellor for research

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

Tehran University of Medical Sciences

Full name of responsible person

Fateme Tavakolnejad

Position

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Person responsible for scientific inquiries

Contact

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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