Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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
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

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
Assistant ENT

Other areas of specialty/work

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Emam Khomeini hospital, Keshavarz s., Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mmohamad Sadeghi

Position
Faculty member of ENT departmenr

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Resident of ENT department

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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