

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison the effect of different Antrostomy and Sphenoidotomy size creation on postoperative mucosal edema and polyp growth rate in paranasal sinuses in patient with chronic rhinosinusitis and polyposis

Protocol summary

Summary

Objectives: Evaluation of Antrostomy and Sphenoidotomy size on polyposis recurrence and mucosal edema after surgery. **Design:** This study is a clinical trial among 210 20-50 year old patients with chronic rhinosinusitis and polyposis candidate for surgery. Patients are classified in 3 groups by another resident randomly through sortition. Surgeon will be informed about the type of intervention in operating room. We have 70 patients in each group. Three groups include: 1:Antrostomy less than 1 cm and sphenoidotomy less than 0.5 cm 2:Antrostomy 1-2 cm and sphenoidotomy 0.5 -1 cm 3:Antrostomy 2-3 cm and sphenoidotomy 1-1.5 cm. All surgeries will be done in Amir Aalam hospital by one surgeon. **Setting and Interventions:** Measurement of size between two device around ostium will be done by a ruler. Seven to ten days after group selection and surgery, mucosal lymphedema will be assessed and polyposis recurrence will be evaluated monthly in first 3 months and every 6 weeks in next three months (up to 6 months) using endoscope in clinic. Edema grading will be: (Grade 1:no lymph edema, Grade2:lymph edema without obstruction, Grade 3:lymph edema with obstruction) Recurrence grading will be: (Grade1:no polyp growth, Grade2:polyp growth without obstruction, Grade3: polyp growth with obstruction). **Inclusion criteria:** 20-50 year old patients with chronic rhinosinusitis and polyposis in more than 3 sinuses including maxilla and sphenoid that need surgery after all diagnostic and therapeutic processes. **Exclusion criteria:** limited disease, collagenvascular disease, allergy, asthma, ASA sensitivity, immune disorder, smoking and toxin exposure and patients without tendency to join to this study. **Primary outcome** is recurrence rate and edema and secondary outcome is further surgeries.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090723936N1**

Registration date: **2017-06-16, 1396/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-16, 1396/03/26

Registrant information

Name

Mohsen Naraghi

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 1376

Email address

naraghim@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of different Antrostomy and Sphenoidotomy size creation on postoperative mucosal edema and polyp growth rate in paranasal sinuses in patient with chronic rhinosinusitis and polyposis

Public title

Effect of sinuses ostium on post surgical outcomes.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20-50 years old patients with chronic rhinosinusitis with polyposis in more than 3 sinuses including maxilla and sphenoid that need surgery after all diagnostic and therapeutic processes. Exclusion criteria: limited disease; collagenvascular disease; allergy; asthma; ASA sensitivity; immune disorder; smoking and toxin exposure and patients without willingness to participate in research.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Patients are distributed in 3 groups like previously description. This is done randomly by third person that don't interfere in surgery. After choosing for surgery patients will refer to other room and are classified in 3 groups by another resident randomly and with balloting. Post operative endoscopy is done by second person that don't have any intervention in previous steps.

Secondary Ids

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Floor 1, Tehran University of Medical Sciences, Ethics committee of Tehran University of Medical Sciences, in front of Avesta park, Azadi street, Tehran

City

Tehran

Postal code**Approval date**

2017-04-05, 1396/01/16

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2034.

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

chronic rhinosinusitis

ICD-10 code

J32.4

ICD-10 code description

Chronic pansinusitis

2**Description of health condition studied**

sinonasal polyposis

ICD-10 code

J33

ICD-10 code description

Nasal polyp

Primary outcomes**1****Description**

edema

Timepoint

monthly in first 3 month and then every 6 weeks

Method of measurement

endoscopic view

2**Description**

recurrence

Timepoint

monthly in first 3 month and then every 6 weeks

Method of measurement

endoscopic view

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Antrostomy size less than 1 cm and sphenoidotomy size less than 0.5 cm that is measured between two devices around ostium by a ruler.

Category

Treatment - Surgery

2

Description

Intervention group 2: Antrostomy size less than 1-2 cm and sphenoidotomy size 0.5-1 cm that is measured between two devices around ostium by a ruler.

Category

Treatment - Surgery

3

Description

Intervention group 3: Antrostomy size less than 2-3 cm and sphenoidotomy size 1-1.5 cm that is measured between two devices around ostium by a ruler.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Aalam Hospital in Tehran

Full name of responsible person

Dr Mehrnoosh Mousaviagdas

Street address

Endoscopy clinic, Tehran Amir Aalam Hospital, Saadi Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr Masood Younesian

Street address

Floor 6, Vice chancellor for research, Tehran University of Medical Sciences, Keshavarz boulevard, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for research of Tehran University of Medical Sciences

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

Amir Aalam hospital

Full name of responsible person

Mehrnoosh Mousaviagdas

Position

Rhinologist

Other areas of specialty/work

Street address

Tehran Amir aalam hospital, Saadi street, Tehran

City

Tehran

Postal code

Phone

+98 21 6670 6106

Fax

Email

mehr_mousavi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Amir aalam hospital

Full name of responsible person

Mohsen Naraghi

Position

Professor of otorhinolaryngology

Other areas of specialty/work

Street address

Amir aallam hospital, Saadi street, Tehran

City

Tehran

Postal code

Phone

+98 21 6670 6106

Fax

Email

naraghim@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Amir aalam hospital

Full name of responsible person

Mehrnoosh Mousaviagdas

Position

Rhinology resident

Other areas of specialty/work**Street address**

Amir aalam hospital, Saadi street, Tehran

City

Tehran

Postal code**Phone**

+98 21 6670 6106

Fax**Email**

mehr_mousavi@yahoo.com

Web page address

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