Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of middle nasal meatus adhesion and middle turbinate position in patients with chronic sinusitis with polyposis, after functional endoscopic sinus surgery (FESS) in the modified splint and control groups

Protocol summary

Study aim

Comparison of middle meatus adhesion and middle turbinate position in patients with chronic sinusitis with polyposis after functional endoscopic sinus surgery in modified splint and control groups

Design

A randomized, parallel-group, unblinded, phase 2-3 clinical trial on 53 patients (106 nostrils). The rand function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted at Besat Hospital, Hamadan. The left and right sides of the nose will be randomly assigned to the group with or without the modified splint. In the modified splint group, a 2 mm thick Silastic splint from Richard will be used. All patients will be discharged on the first day after surgery. Oral antibiotics for 2 weeks, budesonide nasal spray two puffs every 12 hours, cetirizine tablet one daily, and nasal irrigation with saline three times daily are recommended. The modified splint will be removed 7 days after surgery by the resident under local anesthesia for all patients.

Participants/Inclusion and exclusion criteria

Participants are patients with chronic sinusitis with polyposis. Inclusion criteria are age over 18 years, chronic sinusitis with bilateral nasal polyps, and failure to respond to drug therapy. Exclusion criteria: previous history of endoscopic sinus surgery, allergic fungal sinusitis, known primary immunodeficiency, patients who need to undergo septoplasty, and need for additional packing with mesh.

Intervention groups

One side of the nose will have a modified splint inserted into the middle meatus after the end of FESS. The control group is the other side of the nose will not have a modified splint inserted into the middle meatus.

Main outcome variables

The primary outcome of the study is the turbidity of the middle meatus, Discharge, the amount of nasal crusting, and the recurrence of the disease after endoscopic sinus surgery are other outcomes of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N47**
Registration date: **2025-08-08, 1404/05/17**
Registration timing: **prospective**

Last update: **2025-08-08, 1404/05/17**
Update count: **0**

Registration date

2025-08-08, 1404/05/17

Registrant information

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Name of organization / entity

Hamedan University of Medical Of Science

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2026-06-20, 1405/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of middle nasal meatus adhesion and middle turbinate position in patients with chronic sinusitis with polyposis, after functional endoscopic sinus surgery (FESS) in the modified splint and control groups

Public title

Adhesion of the middle nasal meatus and position of the middle turbinate in patients with chronic sinusitis with polyposis, after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic sinusitis with bilateral nasal polyps Failure to respond to drug treatment Age 18 years and above Patient consent to participate in the study

Exclusion criteria:

Previous history of endoscopic sinus surgery Allergic fungal sinusitis Known cases of primary immunodeficiency Patients requiring septoplasty Need more packing with mesh

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **53**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a card number is prepared and 53 letters are written on IR and 53 letters are written on IL, each of which is placed in an envelope with an aluminum cover, the lid is taped and placed in a box. When the patients arrive, one of the envelopes will be randomly selected and opened by the ward nurse. If the selected letters are IR, the right nostril will be corrected by the splint and the left will be the control group. If the selected letters are IL, the left nostril will be corrected by the splint and the right will be the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan Univercity of Medical Science

Street address

Sahahid Fahmideh

City

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Hamadan

Postal code

6517838697

Approval date

2025-05-24, 1404/03/03

Ethics committee reference number

IR.UMSHA.REC.1404.120

Health conditions studied

1

Description of health condition studied

Chronic sinusitis with polyposis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Adhesions of the middle nasal meatus

Timepoint

7 days, 1 month, and 3 months after surgery

Method of measurement

Nasal endoscopy and viewing endoscopic images

2

Description

Nasal discharge and crusting

Timepoint

7 days, 1 month, and 3 months after surgery

Method of measurement

Ask the patient about an intranasal examination

3

Description

Recurrence of sinusitis

Timepoint

One month and 3 months after surgery

Method of measurement
Clinical examination, patient questioning, sinus endoscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A modified splint is used on the intervention side. A phenylephrine-impregnated patch is placed in the nose to establish hemostasis, and then it is removed during recovery. In these patients, a 2 mm thick Richard brand silastic splint is used. After the surgery is completed, the distance from the columella edge to the axilla is measured using a surgical ruler, and then the splint is cut half to one centimeter longer than the measurement from the distal end. The upper edge of the splint is resected to locate the maximum thickness of the splint in the middle meatus (spacer). After the splint is cut and trimmed, it is inserted under the vision of the endoscope in such a way that the distal part of the middle meatus space is completely subaxillary. Then the splint is sutured and fixed at two points using 3-0 nylon cut sutures, and then it is evaluated again by the endoscope to ensure correct placement. Then a phenylephrine-impregnated patch is inserted to establish hemostasis. It is removed during recovery.
Category
Treatment - Devices

2

Description
Control group: In the control group or contralateral nose, the modified splint is not used.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Javaneh Jahanshahi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
MSc in epidemiology/ Comunity Medicine MS
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Master
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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data can be shared except for authors names

When the data will become available and for how long
From 2026 onwards it is permissible

To whom data/document is available
Clinical professionals and Researchers in all fields

Under which criteria data/document could be used
For treatment of patients and develop research and science

From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study

What processes are involved for a request to access data/document
Send and receive email

Comments