

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 randomization 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

##### Name

Abbas Moradi

##### Name of organization / entity

Hamedan University of Medical Of Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0097

##### Email address

a.moradi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### 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

Hamadan

##### Province

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

##### Street address

Shahid Beheshti Blvd

##### City

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##### Province

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##### Postal code

6514845411

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+98 81 3264 0030

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## Email

Besat@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Alireza Soltanian

##### Street address

Shahid Fahmide

##### City

Hamadan

##### Province

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##### Postal code

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##### Email

vc\_research@umsha.ac.ir

##### Web page address

##### 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/ Community Medicine MS

##### Latest degree

Master

##### Other areas of specialty/work

Epidemiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Javaneh Jahanshahi  
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Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Abbas Moradi  
**Position**  
MSc in epidemiology/ Community Medicine MS  
**Latest degree**

Master  
**Other areas of specialty/work**  
Epidemiology  
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**Web page address**

## 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