

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### • Investigating the Results of Betamethasone Ophthalmic Ointment in Polypoid Frontal Sinus in Endoscopic Sinus Surgery and Its Effect in Reducing the Recurrence of Polyposis After Surgery

#### Protocol summary

##### Study aim

The results of using betamethasone ophthalmic ointment in polypoid frontal sinus in endoscopic sinus surgery and its effect in reducing polyp recurrence after surgery.

##### Design

- Two arm parallel group randomized trial with blinded postoperative care and outcome assessment with generating random numbers in 30 patients

##### Settings and conduct

30 patients with bilateral polypoid frontal sinuses with almost the same size were selected in a certain period of time in two teaching hospitals of Iran University of Medical Sciences. Two visits are made after surgery. The first visit is one and a half months and the second visit is after three months in order to check the endoscopic indicators of discharge/inflammation/polyps (DIP) and sinus CT scan. In this study, betamethasone ophthalmic ointment is placed inside the sinus using frontal sinus suction after opening the frontal recess on the side of intervention. The patient and outcome evaluator are blinded by double masked blind method.

##### Participants/Inclusion and exclusion criteria

Bilateral polypoid frontal sinus, The size of frontal sinuses should be approximately the same in each patient, No allergy to corticosteroides, No previous surgery of frontal sinus

##### Intervention groups

In one patient, one frontal sinus is considered as the control group and the other side as the intervention group. In the intervention group, betamethasone ophthalmic ointment is used after polyp removal. In the control group, only the polyp is removed.

##### Main outcome variables

Polyp; Inflammation; Edema; Discharge; Opacification in CT Scan; Soft tissue density ratio in CT Scan

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220510054810N1**

Registration date: **2023-05-21, 1402/02/31**

Registration timing: **retrospective**

Last update: **2023-05-21, 1402/02/31**

Update count: **0**

##### Registration date

2023-05-21, 1402/02/31

##### Registrant information

##### Name

Zeinab Emamgholizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3362 0386

##### Email address

l.med.tbz90@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-05-20, 1402/02/30

##### Actual recruitment start date

2022-09-23, 1401/07/01

##### Actual recruitment end date

2023-04-19, 1402/01/30

##### Trial completion date

2023-05-10, 1402/02/20

## Scientific title

- Investigating the Results of Betamethasone Ophthalmic Ointment in Polypoid Frontal Sinus in Endoscopic Sinus Surgery and Its Effect in Reducing the Recurrence of Polyposis After Surgery

## Public title

- " Investigating the Effect of Betamethasone Ophthalmic Ointment in Reducing the Recurrence of Polyposis After Frontal Sinus Surgery"

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Bilateral Polypoid Frontal sinus The size of the frontal sinuses should be approximately the same in each patient. No allergy to corticosteroides

### Exclusion criteria:

Previous surgery of the frontal sinus Allergy to corticosteroides

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Randomly, in one participant, one frontal sinus is the control sample and the other sinus is the intervention sample.

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Randomly, in one participant, one frontal sinus is the control sample and the other sinus is the intervention sample

## Randomization (investigator's opinion)

Randomized

## Randomization description

Sampling is by random number generation method so that right frontal sinus is selected with odd numbers and left frontal sinus with even numbers.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients know that betamethasone ointment is used in sinus surgery, but they don't know if it is left or right. The evaluator of the result does not know which side the betamethasone ointment was used on.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical science

##### Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran 14496-14535, IRAN

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Approval date

2021-04-06, 1400/01/17

#### Ethics committee reference number

IR.IUMS.FMD.REC.1400.037

## Health conditions studied

### 1

#### Description of health condition studied

Polyp recurrence after sinus surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Polyp recurrence

#### Timepoint

After surgery, two visits are performed, the first one after one and a half months and the second one after three months in order to check the endoscopic parameters including polyps/inflammation/discharges and CT scan indicators of the sinuses.

#### Method of measurement

Using endoscopic examination and polyp, inflammation, discharge (PID) criteria and sinus CT scan to measure soft tissue density ratio (STDR)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 30 patients with bilateral frontal sinus polyps are selected according to the initial CT scan.

Right or left sinus is randomly selected as intervention group. Betamethasone ophthalmic ointment of Iran Najo Pharmaceutical Company 0.1%, 3 grams is used in all patients, which contains 3 milligrams of corticosteroids. After performing Draf 2a surgery in both the control and interventional frontal sinuses in all patients, 3 grams of betamethasone ophthalmic ointment is placed inside the frontal sinus suction and enters the interventional side at the end of the surgery. Ointment is not used in the control sinus. In post-surgery treatment, patients receive budesonide intranasal corticosteroid spray every 12 hours and washing serum. None of the patients receive oral corticosteroids after surgery.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: In this group, during endoscopic sinus surgery, only polyps are removed, and we perform draf 2 a surgery. Betamethasone ointment is not used.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasool Akram Hospital

##### Full name of responsible person

Zeinab Emamgholizadeh

##### Street address

Rasool Akram Hospital, Niyayesh St., Sattarkhan St.

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۵۶۱۳۱۳۱

##### Phone

+98 21 6435 1000

##### Email

Rasoolhospital@iums.ac.ir

##### Web page address

<https://hrmc.iums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Firoozgar Hospital

##### Full name of responsible person

Zeinab Emamgholizadeh

##### Street address

Firoozgar Hospital, Beh Afarin St., Valiasr Square. .

##### City

Tehran

##### Province

Tehran

#### Postal code

۱۵۹۳۷۴۷۸۱۱

#### Phone

+98 21 8214 1000

#### Email

firoozgarhospital1@gmail.com

#### Web page address

<https://firoozgar.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hossein Keyvani

##### Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran 14496-14535, IRAN

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 2030

##### Email

lvco@iums.ac.ir

##### Web page address

<https://iums.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Zeinab Emamgholizadeh

##### Position

Resident

##### Latest degree

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Iran University of Medical Sciences., Shahid Hemmat Highway.,Tehran., IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

info@iums.ac.ir

**Web page address**

https://iums.ac.ir/

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zeinab Emamgholizadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Iran University of Medical Sciences., Shahid Hemmat Highway.,Tehran., IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

L.med.tbz90@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zeinab Emamgholizadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Iran University of Medical Sciences., Shahid Hemmat Highway.,Tehran., IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

l.med.tbz90@gmail.com

**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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

Information About Age and Gender and the Results of Endoscopy and CT Scan Will Be Published.

**When the data will become available and for how long**

3 Months After the Publication of the Results

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

For research

**From where data/document is obtainable**

Zeinab Emamgholizadeh e- mail address:

L.med.tbz90@gmail.com

**What processes are involved for a request to access data/document**

After receiving the email, the requested items will be sent immediately to the email of the document requester. e-mail address : L.med.tbz90@gmail.com

**Comments**