Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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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

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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

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Recruitment center

Name of recruitment center

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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

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
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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
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