Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Comparative assessment of the effect of corticosteroid in three forms of Budesonide nasal spray, Betamethasone nasal drop, and Budesonide nebulizing suspension on sinonasal polyposis recurrence after the FESS

Protocol summary

Study aim

Determining the effect of Budesonide nasal spray in comparison with Betamethasone nasal drops and Budesonide nebulizing suspension on sinonasal polyposis recurrence

Design

108 patients who underwent FESS are randomly assigned to three study groups (36 patients in each group). Patients in all three groups are given cephalexin and rinsing serum in the first two weeks and routine corticosteroid treatment up to one month after surgery. The first diagnostic endoscopy is done two weeks after surgery, and patients are given either drop, spray, or solution according to their treatment group. Then, after 1 and 6 months, re-endoscopy and Modified L K-SCALE are done and results are compared.

Settings and conduct

108 patients with sinonasal polyposis who underwent FESS in Taleghani-Hospital, Tehran are assigned to three treatment groups, including Budesonide nasal spray, Betamethasone nasal drops, and Budesonide nebulizing suspension, using blocked randomization method. Then, 1 and 6 months after surgery, study groups are compared for outcomes. Blindness is not possible in this study due to the nature of interventions.

Participants/Inclusion and exclusion criteria

Sinonasal polyposis patients who candidate for FESS, between 18 to 70 years old; Absence of underlying diseases, including CF, Wegener's, Kartagener, sarcoidosis, vasculitis, or rheumatic diseases; Patients with sinonasal polyposis confirmed by preoperative history, endoscopy, and CT-scan; Receiving no systemic corticosteroids for up to 4 weeks before surgery

Intervention groups

Patients are assigned to three groups, including Budesonide nasal spray (as standard treatment), Betamethasone nasal drops, and Budesonide nebulizing suspension.

Main outcome variables

VAS, patients' self-satisfaction with the surgery results, degree of rhinosinusitis polyps, complications (frequency and degree of recurrence, dry nose, Epistaxis), need to revision

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201021049095N1**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Najmeh Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8806 4168

Email address

najmeh.rajabi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment of the effect of corticosteroid in three forms of Budesonide nasal spray, Betamethasone nasal drop, and Budesonide nebulizing suspension on sinonasal polyposis recurrence after the FESS

Public title

Comparison of the effect of Budesonide nasal spray, Betamethasone nasal drop, and Budesonide nebulizing suspension on sinonasal polyposis recurrence

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

FESS candidates with sinonasal polyposis patients between 18 to 70 years old

Exclusion criteria:

Absence of underlying diseases, including CF, Wegener's, Kartagener, sarcoidosis, vasculitis, or rheumatic diseases; Receiving no systemic corticosteroids for up to 4 weeks before surgery; ages below 18 or higher than 70 years olds

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 108 patients with the study inclusion criteria were randomly assigned to three groups of 36 patients, including Budesonide nasal spray as the standard treatment in comparison with two intervention groups of Betamethasone nasal drop, and Budesonide nebulizing suspension. To begin with, one of the letters A, B, C is considered for each treatment, and Random Allocation software is used to build random blocks. The software generates 18 different blocks with size 6, according to the total sample size of 108, the blocks size of 6, and considering 3 treatment groups. There are 6 blanks in each block in which the 3 letters A, B, and C are randomly combined in different sequences, assuming that each letter is repeated twice in each block. Thus, the software output is a list of 18 blocks, each of which has 6 blanks, which are filled with different sequences of A, B, and C (each letter is repeated twice in every single block). In other words, we have a total of 18 blocks, each of which has 2 locations for every study treatment. Finally, by completing the sampling, we reach 36 patients in each of groups A, B and, C. Next, each block is placed in separate envelopes, encoded from 1 to 18. To maintain the principles of allocation concealment, the physician is not aware of the sequence inside each envelope. The envelopes are given to someone outside the research team who informs the physician about assigning each patient to treatment groups during the study.

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 Shahid-Beheshti University of Medical Sciences

Street address

Qods city, Simaye-Iran St., MOHME

City

Tehran

Province

Tehran

Postal code

3848176941

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.SBMU.MSP.REC.1399.782

Health conditions studied

1

Description of health condition studied

Sinonazal polyposis

ICD-10 code

J33.9

ICD-10 code description

Nasal polyp, unspecified

Primary outcomes

1

Description

recurrence

Timepoint

1 and 6 months after surgery

Method of measurement
Diagnostic endoscopy

2

Description
degree of recurrence
Timepoint
1 and 6 month after surgery
Method of measurement
Modified L K –SCALE endoscopy

3

Description
Visual Analog Scale (VAS) for scoring the symptoms of sinusitis and polyps
Timepoint
1 and 6 months post operation
Method of measurement
questioning from patients

4

Description
self rated satisfaction of surgery outcomes
Timepoint
1 and 6 months post surgery
Method of measurement
questioning from patients

5

Description
need to revision
Timepoint
1 and 6 months post surgery
Method of measurement
examination and questioning from patients

Secondary outcomes

1

Description
side effects including dryness and Epistaxis
Timepoint
1 and 6 months after surgery
Method of measurement
clinical examination

Intervention groups

1

Description
Intervention group: Betamethasone nasal drop 0.1%- Daroopakhsh Company (3 drops on each side of the nose, once per night). In addition, Cephalexin and Lavage serum are given to the patients in all groups during the first two weeks of treatment. As well, routine corticosteroid treatment is given to all groups for up to one month after surgery.
Category
Prevention

2

Description
Intervention group: Budesonide nebulizing suspension, with a dose of 0.25 mg/ml in BD form- AstraZeneca Company (every morning and night, ten series with a syringe inside each side of the nose). In addition, Cephalexin and Lavage serum are given to the patients in all groups during the first two weeks of treatment. As well, routine corticosteroid treatment is given to all groups for up to one month after surgery.
Category
Prevention

3

Description
Control group: Budesonide nasal spray, 32 mcg- Razavi Pharmaceutical Services Institute (1 puff per day on each side of the nose). In addition, Cephalexin and Lavage serum are given to the patients in all groups during the first two weeks of treatment. As well, routine corticosteroid treatment is given to all groups for up to one month after surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Taleghani Hospital
Full name of responsible person
Najmeh Rajabi
Street address
Yaman St.
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
research and technology executive of Shahid-

Beheshti University of Medical Sciences

Street address
Yaman St.

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Province
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Postal code
1985717443

Phone
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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Najmeh Rajabi

Position
student

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data could be shared after deleting the patients' names

When the data will become available and for how long

Since the beginning of the data collection

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Data could be shared if other researchers request it

From where data/document is obtainable

Najmeh Rajabi

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

Sending email to the researcher

Comments