Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Comparative Evaluation of the Effects of Betamethasone Drops versus Fluticasone Nasal Spray on Chronic Rhinosinusitis Following Endoscopic Sinus Surgery: A Randomized Controlled Trial

Protocol summary

Study aim

Efficacy of Betamethasone Nasal Drops in Post-Sinus Surgery Patients with Chronic Rhinosinusitis and Nasal Polyps: A Controlled Study"

Design

This clinical trial will include an intervention group and a control group, with a sample size of 80 participants in each group. Blinding: Triple-blind. Randomization: The random allocation sequence with unique codes will be generated using the Sealedenvelope website

Settings and conduct

All patients will have a preoperative CT scan (Lund–Mackay score), SNOT-22 questionnaire, and Lund–Kennedy endoscopic assessment. CBC, glucose, cortisol, ACTH, and IgE will be measured before surgery and at 1, 3, and 6 months. Participants will be recruited at Amir-al-Momenin Educational and Therapeutic Center, Rasht, Iran, during 2025–2026.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18 to 65 years, diagnosed with chronic rhinosinusitis with nasal polyps, who are candidates for endoscopic sinus surgery due to lack of response to maximal medical therapy. Exclusion Criteria: History of prior endoscopic sinus surgery Recent smoking Systemic diseases Hypothalamic-pituitary-adrenal axis dysfunction Central compartment disease Chronic rhinosinusitis without nasal polyps Presence of mucocele History of skull base fractures Patients with glaucoma or increased intracranial pressure

Intervention groups

Intervention groups:The patient received intranasal betamethasone drops together with saline spray as placebo, and intranasal fluticasone spray Control group: The patient received intranasal fluticasone , and saline drops

Main outcome variables

The mean scores of the Lund–Mackay, Lund–Kennedy, and SNOT-22, as well as serum levels of cortisol, ACTH, IgE, WBC, lymphocytes, neutrophils, and eosinophils, will be determined and compared between the study groups at baseline

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048051N5**
Registration date: **2026-06-10, 1405/03/20**
Registration timing: **prospective**

Last update: **2026-06-10, 1405/03/20**
Update count: **0**

Registration date

2026-06-10, 1405/03/20

Registrant information

Name

Malihe Akbarpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-06-22, 1406/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Evaluation of the Effects of Betamethasone Drops versus Fluticasone Nasal Spray on Chronic Rhinosinusitis Following Endoscopic Sinus Surgery: A Randomized Controlled Trial

Public title

A Comparative Evaluation of the Effects of Betamethasone Drops versus Fluticasone Nasal Spray on Chronic Rhinosinusitis Following Endoscopic Sinus Surgery: A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18–65 years sinonasal polyposis involving the frontal recess and bilateral ethmoid sinuses failed to respond to maximal medical therapy surgery candidate

Exclusion criteria:

A prior history of endoscopic sinus surgery (ESS) History of smoking Systemic diseases such as granulomatosis with polyangiitis (GPA), eosinophilic granulomatosis with polyangiitis (EGPA), cystic fibrosis, and primary ciliary dyskinesia Hypothalamic–pituitary–adrenal (HPA) axis dysfunction "Central compartment disease (CCD) Chronic rhinosinusitis without nasal polyps (CRSsNP) Mucocele Previous skull base fracture Patients presenting with glaucoma and increased intracranial pressure (ICP)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **3**

En For all patients, a preoperative CT scan will be performed to evaluate the extent of the disease and to assist in intraoperative planning. The SNOT-22 questionnaire will be administered to all patients at baseline (0 months), 2 months, and 6 months after surgery. Lund-Kennedy endoscopic scoring will be recorded at the same time points (0, 2, and 6 months), and the Lund-Mackay CT score will be assessed preoperatively. Initial laboratory tests, including complete blood count, blood glucose, cortisol, ACTH, and IgE, will be performed for all patients before surgery, and repeated at 1, 3, and 6 months postoperatively.

Randomization (investigator's opinion)

Randomized

Randomization description

Method used for generating the randomization sequence, including the software or website used: To generate a randomization sequence with a unique code, the Sealed Envelope website was used . All eligible patients will be allocated to groups A and B in equal proportions (1:1) using stratified block randomization with block sizes of fou

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants: Patients will be unaware of which treatment they are receiving (betamethasone drops or fluticasone spray). To maintain blinding, identical-looking containers will be used for both medications. Healthcare Providers/Investigators: Physicians and nurses administering the treatments and monitoring patients will also be blinded to the assigned intervention. This ensures that their assessments and interactions are not influenced by knowledge of the treatment. Outcome Assessors/Analysts: Individuals evaluating clinical outcomes, performing endoscopic scoring, and analyzing the data will remain blinded to group allocation until the completion of data analysis. Randomization codes will be securely held by a third-party (e.g., a statistician or independent coordinator) who will not participate in patient care or outcome assessment. Codes will be revealed only after the final analysis is completed

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Guilan University of Medical Sciences

Street address

Deputy of Research and Technology, Guilan University of Medical Sciences, Opposite 17 Shahrivar Hospital, Shahid Siyyadati Street, Namjoo Street, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2026-04-22, 1405/02/02

Ethics committee reference number

IR.GUMS.Rec.1405.045

Health conditions studied

1

Description of health condition studied
CRSwNP patients
ICD-10 code
J32
ICD-10 code description
Chronic sinusitis

Primary outcomes

1

Description
To evaluate the quality of life In two groups of patients with chronic sinusitis with polyposis, who respectively underwent 'endoscopic sinus surgery + fluticasone nasal spray' or 'endoscopic sinus surgery + fluticasone nasal spray + betamethasone nasal drops
Timepoint
Immediately before surgery, and at 3 and 6 months postoperatively"
Method of measurement
Sino-Nasal Outcome Test-22 (SNOT-22) questionnaire

2

Description
evaluate the degree of endoscopic disease involvement In two groups of patients with chronic sinusitis with polyposis, who respectively underwent 'endoscopic sinus surgery + fluticasone nasal spray' or 'endoscopic sinus surgery + fluticasone nasal spray + betamethasone nasal drops
Timepoint
Immediately before surgery, and at 3 and 6 months postoperatively
Method of measurement
The Lund–Kennedy endoscopic scoring system was used to evaluate endoscopic findings in patients with chronic rhinosinusitis

3

Description
Assessment of the extent of involvement and radiologic staging of chronic rhinosinusitis
Timepoint
Immediately before surgery
Method of measurement
The Lund–Mackay scoring system was used to perform radiologic staging in patients with CRS

Secondary outcomes

1

Description
lymphocyte cell
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
The percentage of lymphocytes relative to the total WBC in a CBC test

2

Description
Polymorphonuclear cell
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
The percentage of Polymorphonuclear cell relative to the total WBC in a CBC test

3

Description
WBC cell
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
the total WBC in a CBC test

4

Description
cortisol level
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
The basal serum cortisol level at 8:00 a.m. while fasting, for which the normal range is 1-25 micrograms per deciliter

5

Description
ACTH Level
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
The basal serum adrenocorticotropic hormone level at 8:00 a.m. while fasting, for which the normal range is 9 to 52 picograms per milliliter.

6

Description
IgE level
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
International Unit per milliliter

7

Description
eosinophil cell
Timepoint
immediately before surgery, and at 2 and 6 months postoperatively
Method of measurement
The percentage of eosinophil cell relative to the total WBC in a CBC test

Intervention groups

1

Description
Intervention group: The patient received intranasal betamethasone drops (three drops in the morning) together with saline spray as placebo, and intranasal fluticasone spray (two puffs at night).
Category
Treatment - Drugs

2

Description
Control group: : The patient received intranasal fluticasone spray, administered as two puffs every 12 hours, and saline drops (three drops in the morning), which were used as placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Hossein Ramzannejad
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Amir-al-Momenin Hospital, 17 Shahrivar Street, Dr. Heshmat Square, Rasht, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. seyed ali alavi
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Deputy of Research and Technology, Guilan University of Medical Sciences, Opposite 17 Shahrivar Hospital, Shahid Siyyadati Street, Namjoo Street, Rasht, Iran
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Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Guilan 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
Rasht University of Medical Sciences
Full name of responsible person
Hossein Ramzannejad
Position
ENT resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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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

No - There is not 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

Yes - There is 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

Data will be shared comprehensively and will include all the variables mentioned above, not being limited to only the primary outcomes. Following the removal of all direct identifiers (such as name, medical record number, national identification code) and the application of ethical considerations, these data will be made available to researchers for legitimate research purposes

When the data will become available and for how long

The data and document access period will begin from the project's completion and after the initial results are published in a scientific article. This access will be available for a minimum of 5 years after the project's end date.

To whom data/document is available

Access to the de-identified data from this research will be provided to researchers and investigators affiliated with academic institutions, scientific research centers, or healthcare-therapeutic organizations. Requests for access must have a valid scientific justification and clear research objectives, and must be approved by an independent ethics review committee. This access does not include researchers working in industry (pharmaceutical or medical device industries), except within the framework of approved scientific collaborations with the university and with full adherence to ethical considerations and confidentiality preservation

Under which criteria data/document could be used

The data and documents from this research will be accessible solely for research and academic purposes, including conducting secondary studies, meta-analyses, validation of findings, and educational objectives (with proper citation). Applicants must submit a written request along with a detailed research proposal and provide a certificate of approval from the ethics committee of their affiliated institution. Commercial use of the data in any form is not permitted, and the applicant is required to sign an agreement ensuring confidentiality, citing the original source in all publications, refraining from re-identifying participants, submitting draft manuscripts to the principal investigator prior to publication, not transferring data to third parties, and deleting the data upon project completion. All requests will be evaluated and subject to final decision by the Research Oversight Committee.

From where data/document is obtainable

To access the data and documents from this research, applicants can submit their requests in order of priority via email to akbarpour_malihe@yahoo.com with the subject line "Request for Access to Chronic Rhinosinusitis Research Data" addressed to Dr. Malihe Akbarpour (Principal Investigator). If a telephone call is necessary, contact can be made at 09001311808 from Saturday to Wednesday between 10:00 and 14:00. Additionally, written requests can be sent by mail to the following address: Guilan Province, Rasht City, Amir al-Momenin Hospital, Otorhinolaryngology Research Center, Postal Code: [Exact postal code to be specified according to hospital protocol], Attn: Dr. Malihe Akbarpour. It should be noted that all requests must include a detailed research proposal, ethics committee approval, and complete contact information, with email communications receiving priority processing. All received requests will be reviewed and evaluated by the principal investigator and the Research Oversight Committee at Guilan University of Medical Sciences.

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

The process for requesting access to the data from this research is a multi-stage procedure that typically takes 5 to 8 business weeks to complete. After the applicant submits a complete request (including the research proposal, ethics approval, and contact information), an initial review is conducted by the principal investigator. If necessary, supplementary correspondence will take place and a Data Use Agreement will be sent (1 to 2 weeks). The request is then referred to the Research Oversight Committee of Guilan University of Medical Sciences for scientific and ethical evaluation (2 to 4 weeks). Following final approval by the committee (1 week), if approved, the de-identified data will be delivered in processable file formats through secure methods (1 week). It should be noted that this timeframe may vary slightly depending on the volume of requests and the committee's meeting schedule. The status of the request can be followed up via email at akbarpour_malihe@yahoo.com.

Comments