Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Short- and Long-Term Clinical and Endoscopic Outcomes of Postoperative Systemic Prednisolone versus Placebo in Patients with Nasal Polyposis

Protocol summary

Study aim
The main objective of this study is to evaluate the effect of systemic prednisolone after surgery on short- and long-term clinical and endoscopic outcomes in patients with nasal polyposis compared with the control group.

Design
A Phase II-III, double-blind, randomized, parallel-group clinical trial on 60 patients. All patients will receive preoperative prednisolone and undergo surgery. The intervention group will receive postoperative prednisolone, and the control group will receive a postoperative placebo. Block randomization with a block size of 4 will be used for randomization.

Settings and conduct
Patients will be divided into two groups. All patients will receive 20 mg of prednisolone for seven days before surgery and then undergo surgery; the intervention group will receive prednisolone and the control group will receive a placebo for 28 days after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with chronic rhinosinusitis with nasal polyps (CRSwNP) Candidates for functional endoscopic sinus surgery (FESS) Exclusion criteria: Autoimmune diseases

Intervention groups
In this study, conducted at Imam Reza Hospital in Tabriz, patients who are candidates for nasal polyposis surgery will be divided into two groups: Group A, who will receive prednisolone before surgery, undergo surgery, and receive prednisolone after surgery; and Group B, who will receive only a placebo after surgery. This process will be carried out based on the specialist’s decision and will be performed by them.

Main outcome variables
Nasal Polyp Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N89**
Registration date: **2026-09-26, 1405/07/04**
Registration timing: **prospective**

Last update: **2026-09-26, 1405/07/04**
Update count: **0**

Registration date
2026-09-26, 1405/07/04

Registrant information
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-06, 1405/07/14

Expected recruitment end date
2027-03-05, 1405/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Short- and Long-Term Clinical and Endoscopic Outcomes of Postoperative Systemic Prednisolone versus Placebo in Patients with Nasal Polyposis

Public title
The short-term and long-term outcomes of systemic prednisolone administration after nasal polypectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Chronic Rhinosinusitis with Nasal Polyps Patients with Chronic Rhinosinusitis with Nasal Polyps undergoing FESS
Exclusion criteria:
Autoimmune Diseases Autoimmune Diseases
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, with a sample size of 60 , participants will be assigned to three groups using permuted block randomization. A block size of four will be employed, utilizing all possible combinations, including: Block 1 (BBAA), Block 2 (AABB), Block 3 (ABAB), Block 4 (BABA), Block 5 (ABBA), and Block 6 (BAAB). To accommodate 60 participants, 15 blocks will be generated using Random Allocation Software, with blocks randomly selected from numbers 1 to 6. For instance, if block 6 and block 2 are selected sequentially, the allocation sequence will be BAABAABB, assigning individuals to Intervention Group (A) and the Control Group(B). To ensure allocation concealment, the randomization list will be prepared and numbered by an independent researcher who is not involved in patient recruitment or assessment. The assignments will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). The study investigator will open the envelopes in numerical order only after a patient has been formally enrolled and their code has been recorded, ensuring that the allocation sequence remains unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, to ensure proper patient blinding, the medications for groups A and B will be prepared in identical appearance, color, packaging, and administration method, making them indistinguishable to participants. Each medication will be labeled with a unique code (A or B), known only to an independent researcher who is not involved in patient recruitment or evaluation. The envelopes containing the coded medication will be provided to the study investigator in sequential order, without any indication of treatment type. Consequently, both patients and the investigator will remain unaware of group allocation, thus maintaining a practical and effective double-blind design throughout the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Imam Reza Hospital, Azadi Ave
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5165665631
Approval date
2026-03-15, 1404/12/24
Ethics committee reference number
IR.TBZMED.REC.1404.879

Health conditions studied

1

Description of health condition studied
Nasal Polyp Score
ICD-10 code
J33
ICD-10 code description
Nasal polyp

Primary outcomes

1

Description
Nasal Polyp Score
Timepoint
First, second, third, and sixth month post-surgery
Method of measurement
Nasal Polyp Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive 20 mg of prednisolone daily for seven days prior to surgery and will subsequently undergo surgery. Postoperatively, these patients will receive prednisolone for 28 days.
Category
Treatment - Drugs

2

Description
Control group: Participants in the control group will receive 20 mg of prednisolone daily for seven days prior to surgery and will subsequently undergo surgery. Postoperatively, these patients will receive a placebo for 28 days.
Category
Treatment - Drugs

Recruitment centers

1

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
Tabriz 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available