Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effectiveness of Triamcinolone Plus Normal Saline Nasal Irrigation versus Budesonide Plus Normal Saline Nasal Irrigation on Clinical Outcomes and Quality of Life in Patients with Chronic Rhinosinusitis with Nasal Polyps after Endoscopic Sinus Surgery

Protocol summary

Study aim
To compare the effectiveness of nasal irrigation with triamcinolone plus normal saline versus budesonide nasal spray plus normal saline in reducing postoperative complications in patients with chronic rhinosinusitis with nasal polyps after endoscopic sinus surgery.

Design
A randomized, double blind, parallel group clinical trial including 84 patients. Participants will be allocated using permuted block randomization

Settings and conduct
The study will be conducted at Ayatollah Khansari Hospital and Imam Reza Clinic in Arak, Iran. After surgery, participants will be randomly assigned to one of two groups. Patients, outcome assessors, and data analysts will remain blinded to treatment allocation

Participants/Inclusion and exclusion criteria
Patients with chronic rhinosinusitis with nasal polyps undergoing endoscopic sinus surgery. Inclusion criteria: confirmed diagnosis based on clinical findings and computed tomography scan, written informed consent. Exclusion criteria: anatomical sinus abnormalities or unwillingness to continue participation

Intervention groups
Group one receives budesonide nasal spray plus normal saline irrigation. Group two receives nasal irrigation with triamcinolone mixed with normal saline

Main outcome variables
Sino Nasal Outcome Test 22 score; Lund Kennedy endoscopic score; Lund Mackay computed tomography score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260218068916N1**
Registration date: **2026-07-03, 1405/04/12**
Registration timing: **prospective**

Last update: **2026-07-03, 1405/04/12**
Update count: **0**

Registration date
2026-07-03, 1405/04/12

Registrant information

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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
2026-07-22, 1405/04/31

Expected recruitment end date
2027-04-18, 1406/01/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Triamcinolone Plus

Normal Saline Nasal Irrigation versus Budesonide Plus Normal Saline Nasal Irrigation on Clinical Outcomes and Quality of Life in Patients with Chronic Rhinosinusitis with Nasal Polyps after Endoscopic Sinus Surgery

Public title
Comparison of Triamcinolone and Budesonide Nasal Irrigation after Endoscopic Sinus Surgery in Patients with Chronic Rhinosinusitis with Nasal Polyps

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years or older Diagnosis of chronic rhinosinusitis with nasal polyps Undergoing endoscopic sinus surgery Candidate for postoperative nasal irrigation Willingness to participate and provision of written informed consent

Exclusion criteria:
Known hypersensitivity to triamcinolone or budesonide Pregnancy or breastfeeding Uncontrolled systemic disease interfering with study participation Refusal to participate before randomization Inability to perform nasal irrigation or complete follow-up

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomly allocated to either the intervention group (Triamcinolone plus normal saline nasal irrigation) or the control group (Budesonide plus normal saline nasal irrigation) using block randomization with a 1:1 allocation ratio. The randomization unit is the individual participant. No stratified randomization will be used. The random allocation sequence will be generated using statistical software. Allocation concealment will be ensured by using sequentially numbered, opaque, sealed envelopes, which will be opened only after the participant has been enrolled in the study

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind randomized clinical trial. Participants and outcome assessors will be blinded to the treatment allocation. The study medications will be prepared in identical containers with coded labels to ensure that the two interventions are indistinguishable in appearance, packaging, and method of administration. The randomization code will be kept by an independent researcher who is not involved in patient recruitment, outcome assessment, or data analysis. The allocation code will remain concealed until completion of data collection and primary statistical analysis, unless unblinding is required for patient safety.

Placebo
Not used

Assignment
Parallel

Other design features
This is a randomized, parallel-group clinical trial designed to compare the effectiveness of triamcinolone plus normal saline nasal irrigation with budesonide plus normal saline nasal irrigation in patients with chronic rhinosinusitis with nasal polyps following endoscopic sinus surgery

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Prophet Azam Campus, Km 5, Khomein Road, Arak, Markazi Province, Iran.

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Province
Markazi

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Approval date
2025-05-21, 1404/02/31

Ethics committee reference number
IR.ARAKMU.REC.1404.300

Health conditions studied

1

Description of health condition studied
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

ICD-10 code
J33

ICD-10 code description
Nasal polyp

Primary outcomes

1

Description
Change in the Sino-Nasal Outcome Test-22 questionnaire score

Timepoint
Before surgery, one month after surgery, and three

months after surgery

Method of measurement

Measured using the standardized Sino-Nasal Outcome Test-22 questionnaire completed by the patient.

Secondary outcomes

1

Description

Change in nasal endoscopic findings based on the Lund–Kennedy scoring system

Timepoint

Before surgery, one month after surgery, and three months after surgery

Method of measurement

Assessed by an otorhinolaryngologist using the standard Lund–Kennedy endoscopic scoring system

Intervention groups

1

Description

Intervention group: After endoscopic sinus surgery, participants receive nasal irrigation with a solution containing triamcinolone and 0.9% normal saline. The solution is prepared by dissolving 80 mg of triamcinolone (two 40-mg ampoules) in one liter of normal saline. Patients irrigate each nostril with 10–15 mL of the solution every 6 hours for three months

Category

Treatment - Drugs

2

Description

Control group: After endoscopic sinus surgery, participants receive the standard treatment consisting of budesonide nasal spray (two sprays in each nostril every 12 hours, 64 micrograms per spray) together with nasal irrigation using 0.9% normal saline (10–15 mL per nostril every 6 hours) for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khansari Hospital

Full name of responsible person

Benyamin Rahmaty

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Amir Hossein Kiani

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data (IPD) will not be shared due to confidentiality considerations, ethical requirements, and the limitations specified in the informed consent form. No further information is 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
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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