

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparing the effects of zinc supplementation on reducing polyp recurrence in patients with chronic rhinosinusitis and inflammatory and allergic nasal polyps referred to Taleghani Hospital

Protocol summary

Study aim

Comparing the effects of zinc supplementation on reducing polyp recurrence in patients with chronic rhinosinusitis and inflammatory and allergic nasal polyps referred to Taleghani Hospital

Design

This study is a phase 1-2, randomized, single-blind, placebo-controlled, parallel-group clinical trial involving 40 patients. Participants will be randomly allocated in a 1:1 ratio to either the intervention group or the placebo group using a block randomization technique.

Settings and conduct

This randomized, placebo-controlled trial will enroll patients with chronic rhinosinusitis and allergic/inflammatory nasal polyps from Taleghani Hospital. Participants will be randomly assigned to either the treatment or placebo group, with strict blinding maintained to prevent bias in outcome assessment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no underlying systemic conditions. Additionally, must not have taken zinc supplements within the past 3 months. Exclusion criteria: lost to follow-up after surgery, if histopathological examination revealed any diagnosis other than sinonasal polyposis, or if they failed to adhere to the prescribed postoperative medication regimen.

Intervention groups

Postoperatively, patients in the first group will receive a 1-month course of oral prednisolone at a dose of 0.5 mg/kg of body weight. This will be followed by a 3-month regimen consisting of: 20 mL normal saline nasal irrigation in both nostrils four times daily, topical steroid administration every 12 hours, and one daily 220 mg zinc sulfate capsule (equivalent to 55 mg of elemental zinc) (Alhavipharma company). The second group of patients (control group) will receive the same treatment regimen without zinc sulfate supplementation. Instead of

zinc, they will be given a placebo.

Main outcome variables

Polyp recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042460N1**

Registration date: **2025-05-18, 1404/02/28**

Registration timing: **prospective**

Last update: **2025-05-18, 1404/02/28**

Update count: **0**

Registration date

2025-05-18, 1404/02/28

Registrant information

Name

Matin Ghazizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1317

Email address

matinghazizadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-31, 1404/03/10

Expected recruitment end date

2025-12-01, 1404/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of zinc supplementation on reducing polyp recurrence in patients with chronic rhinosinusitis and inflammatory and allergic nasal polyps referred to Taleghani Hospital

Public title

The effects of zinc supplementation on reducing polyp recurrence in patients with chronic rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Without underlying diseases including cystic fibrosis, Kartagener syndrome, Wegener's vasculitis, vasculitides, sarcoidosis, and rheumatologic diseases. They should not have taken zinc as a dietary supplement in the past 3 months. The patients included in the study must not have received systemic corticosteroid therapy or undergone previous sinus surgery.

Exclusion criteria:

No postoperative follow-up. Any histopathological diagnosis other than sinonasal polyposis (SNP), such as malignancies. No postoperative medication use.

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with neutrophilic and eosinophilic polypoid rhinosinusitis will be equally randomized into intervention and placebo groups in a 1:1 ratio using block randomization technique.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patients are all unaware of the type of intervention being administered to the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

Arabi St, Yaman Ave, Chamran Highway, Tehran

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Tehran

Postal code

1985717413

Approval date

2025-04-29, 1404/02/09

Ethics committee reference number

IR.SBMU.MSP.REC.1404.028

Health conditions studied**1****Description of health condition studied**

Polyp

ICD-10 code

J33

ICD-10 code description

Nasal polyp

Primary outcomes**1****Description**

Polyp recurrence

Timepoint

Before the intervention, and at 1, 3, and 6 months after the intervention

Method of measurement

Clinical examination and Sino-nasal Outcome Test (SNOT-22) questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Postoperatively, patients in the first group will receive a 1-month course of oral prednisolone at a dose of 0.5 mg/kg of body weight. This will be followed by a 3-month regimen consisting of: 20 mL normal saline nasal irrigation in both nostrils four times daily, topical steroid administration every 12 hours, and one daily 220 mg zinc sulfate capsule (equivalent to 55 mg of elemental zinc) (Alhavipharma company).

Category

Treatment - Drugs

2**Description**

Control group: The second group of patients (control group) will receive the same treatment regimen without zinc sulfate supplementation. Instead of zinc, they will be given a placebo.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Taleghani Educational Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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

Matin Ghazizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Highway, Tehran, Iran**City**

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Province

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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**

Not applicable

Informed Consent FormUndecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable