

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of helicobacter pylori treatment versus placebo on the prevention of the recurrence of sinonasal polyps after functional endoscopic surgery: a triple-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of helicobacter pylori treatment versus placebo on the prevention of the recurrence of sinonasal polyps after functional endoscopic surgery

Design

This is a triple-blind randomized clinical trial, phase III, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with sinonasal polyps who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be triple-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Sinonasal polyps, Helicobacter pylori antigen positive
Exclusion criteria: Dyspepsia or peptic ulcer or gastritis, Chronic obstructive pulmonary disease

Intervention groups

Intervention group: Sinonasal polyps surgery by functional endoscopic plus nasal Fluticasone spray one puff every 12 hours, tablet Cefixime 400 mg once daily, tablet Loratadine 10 mg every 12 hours, and nasal irrigation three times daily for 2 weeks as well as Helicobacter pylori treatment with four-drug regimen including capsule Amoxicillin 1 g every 12 hours, tablet metronidazole 500 mg every 12 hours, tablet bismuth 420 mg every 12 hours, and tablet Pantoprazole 40 mg every 12 hours for 2 weeks
Control group: Sinonasal polyps surgery by functional endoscopic plus nasal Fluticasone spray one puff every 12 hours, tablet Cefixime 400 mg once daily, tablet Loratadine 10 mg every 12 hours, and nasal irrigation three times daily for 2 weeks as well as tablet placebo every 12 hours for 2

weeks

Main outcome variables

Primary outcome: The recurrence of sinonasal polyps

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N309**

Registration date: **2019-10-17, 1398/07/25**

Registration timing: **retrospective**

Last update: **2019-10-17, 1398/07/25**

Update count: **0**

Registration date

2019-10-17, 1398/07/25

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of helicobacter pylori treatment versus placebo on the prevention of the recurrence of sinonasal polyps after functional endoscopic surgery: a triple-blind randomized clinical trial

Public title

Effect of helicobacter pylori treatment versus placebo on the prevention of the recurrence of sinonasal polyps after functional endoscopic surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years, Sinonasal polyps, Helicobacter pylori antigen positive

Exclusion criteria:

Dyspepsia or peptic ulcer or gastritis, Chronic obstructive pulmonary disease

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.UMSHA.REC.1397.92

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

Nasal polyp

ICD-10 code

J33

ICD-10 code description

Nasal polyp

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

The recurrence of sinonasal polyps

Timepoint

1 and 3 and 6 months after the intervention

Method of measurement

By endoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sinonasal polyps surgery by functional endoscopic plus nasal Fluticasone spray one puff every 12 hours, tablet Cefixime 400 mg once daily, tablet Loratadine 10 mg every 12 hours, and nasal irrigation three times daily for 2 weeks as well as Helicobacter pylori treatment with four-drug regimen including capsule Amoxicillin 1 g every 12 hours, tablet metronidazole 500 mg every 12 hours, tablet bismuth 420 mg every 12 hours, and tablet Pantoprazole 40 mg every 12 hours for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Sinonasal polyps surgery by functional endoscopic plus nasal Fluticasone spray one puff every 12 hours, tablet Cefixime 400 mg once daily, tablet Loratadine 10 mg every 12 hours, and nasal irrigation three times daily for 2 weeks as well as tablet placebo every 12 hours for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Dr. Aram Toolabi

Street address

Besat Hospital, Shahed Square

City

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Province

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6517838695

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+98 81 3364 0030

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Toolabi_a@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Aram Toolabi

Position

Resident of ENT

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Javaneh Jahanshahi

Position

ENT Specialist

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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