

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of topical vancomycin versus placebo on prevention of sinonasal polyposis recurrence after FESS (Functional Endoscopic Sinus Surgery): A triple blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of topical vancomycin versus placebo on prevention of sinonasal polyposis recurrence after FESS **Design:** A triple blinded randomized clinical trial **Setting and conduct:** The eligible patients with sinonasal polyposis who are candidate for functional endoscopic sinus surgery and will refer to Beasat hospital, in Hamadan City, in 2014 **Inclusion criteria:** (a) having chronic sinusitis in accordance with polyposis; (b) age of 18 to 70 years. **Exclusion criteria:** (a) having immune system disorder; (b) having systemic diseases such as diabetes, chronic renal failure, malignancy, cystic fibrosis, or granulomatosis disease; (c) being pregnant. **Intervention:** Standard treatment (including baclofen nasal spray and loratadine tablet) plus nasal irrigation with 20 ml normal saline solution including 1 gr/l vancomycin, three time a day for eight weeks. **Control:** Standard treatment (including baclofen nasal spray and loratadine tablet) plus nasal irrigation with 20 ml normal saline solution, three time a day for eight weeks **Primary outcome:** Polyposis recurrence in the second, fourth, and sixth months after surgery based on nasal endoscopic criteria. **Secondary outcomes:** (a) Staph aureus infection in nasal cavity in the second month after surgery using sterile soap from medial meatus and microbial culture; (b) drug side effects (including nasal dryness and/or sensitivity) 8 weeks after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312299014N20**

Registration date: **2014-08-16, 1393/05/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-16, 1393/05/25

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

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical vancomycin versus placebo on prevention of sinonasal polyposis recurrence after FESS (Functional Endoscopic Sinus Surgery): A triple blinded randomized clinical trial

Public title

Effect of topical vancomycin versus placebo on prevention of sinonasal polyposis recurrence after FESS (Functional Endoscopic Sinus Surgery)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: (a) having chronic sinusitis in accordance with polyposis; (b) age of 18 to 70 years.
Exclusion criteria: (a) having immune system disorder; (b) having systemic diseases such as diabetes, chronic renal failure, malignancy, cystic fibrosis, or granulomatosis disease; (c) being pregnant.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

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

City

Hamadan

Postal code

6517838695

Approval date

2014-06-17, 1393/03/27

Ethics committee reference number

P/16/35/9/713

Health conditions studied

1

Description of health condition studied

Nasal polyposis

ICD-10 code

J33.0

ICD-10 code description

Polyp of nasal cavity

Primary outcomes

1

Description

Polyposis recurrence

Timepoint

in the second, fourth, and sixth months after surgery

Method of measurement

based on nasal endoscopic criteria

Secondary outcomes

1

Description

Staph aureus infection in nasal cavity

Timepoint

in the second month after surgery

Method of measurement

using sterile soap from medial meatus and microbial culture

2

Description

drug side effects (including nasal dryness and/or sensitivity)

Timepoint

8 weeks after surgery

Method of measurement

Quesytion from patient

Intervention groups

1

Description

Standard treatment (including baclofen nasal spray and loratadine tablet) plus nasal irrigation with 20 ml normal saline solution including 1 gr/l vancomycin, three time a day for eight weeks

Category

Treatment - Drugs

2

Description

Standard treatment (including baclofen nasal spray and loratadine tablet) plus nasal irrigation with 20 ml normal saline solution, three time a day for eight weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Beasat hospital
Full name of responsible person
Dr Javaneh Jahanshahi
Street address
Beasat hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences
Full name of responsible person
Dr saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave
City
Hamadan
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Resident of Ear-Nose-Throat
Full name of responsible person
Dr Javad Yazdani

Position
MD
Other areas of specialty/work
Street address
Beasat hospital, Shahed Square
City
Hamadan
Postal code
Phone
+81 18380090
Fax
Email
hami.yari@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Beasat hospital
Full name of responsible person
Dr Javaneh Jahanshahi
Position
Surgeon of Ear-Nose-Throat
Other areas of specialty/work
Street address
Beasat hospital, Shahed Square
City
Hamadan
Postal code
Phone
+98 81 1838 0090
Fax
Email
J.Jahanshahi@umsha.ac.ir
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty