Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 granolomatosis 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

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Name of organization / entity
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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 granolomatosis 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
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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
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
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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