

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of intranasal amphotericin-B Irrigation on recurrence of massive nasal polyposis after endoscopic sinus surgery and comparison with nasal corticosteroid sprays

Protocol summary

Summary

The purpose of the study is to determine the effect of intranasal amphotericin B solution compared to nasal corticosteroid spray on advanced nasal polyposis recurrence after endoscopic operation on sinus. The patients with corticosteroid dependency, the pregnant or nursing mothers, the mentally retarded or the people with verbal or behavioural disorders will be excluded. Those patients who display any adverse reaction or side-effects during treatment or those who don't complete the 4 month course of drug treatment and those who don't provide the researchers with a written permission will also be excluded. This is a random sampling study on 96 patients (in 2 groups of 48) with more than 15 years old living in Guilan province who suffer serious polyposis of nose whose problem has been diagnosed through physical examination, diagnostic endoscopy & CT scan. All surgical operation are endoscopic along with correction of deviated septum. The day after operation when the patients are being discharged each patient in group A (intervention group) receives Amphotricine B (100 mg/ml) in distilled water kept in a dark bottle and each patient in group B (controls) receives the nasal Beclometazone Spray. The prescription and usage instructions are fully explained to the patients. The patients will be visited one week and one month after the operation followed by monthly visits to examine the nasal polyposis and renew the medication. At the end of the 4 months period the patient will fill in the questionnaire on respiratory problems after operation. Finally each patient will undergo a repeat diagnostic endoscopic operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706101138N1**

Registration date: **2010-09-30, 1389/07/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-30, 1389/07/08

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2012-02-23, 1390/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of intranasal amphotericin-B Irrigation on

recurrence of massive nasal polyposis after endoscopic sinus surgery and comparison with nasal corticosteroid sprays

Public title

Effects of intranasal amphotericin-B Irrigation on recurrence of massive nasal polyposis

Purpose

Treatment

Inclusion/Exclusion criteria

The study population consists of patients more than 15 years old residents of Guilan province who have extensive nasal polyposis and their diseases are diagnosed based on physical examination, diagnostic nasal endoscopy, and CT scan of paranasal sinuses. Only those patients who would complete the 4 months course of drug therapy and undergo the follow- up visits, will enter in the study. Those patients who are depended to corticosteroid drugs, pregnant or breast-feeder women, mental retard cases, or patients with speech or behavioral disorders will be excluded from the study. Every patients who enter the study must fulfill informed consent.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Shahid Siadati st.- Rasht

City

Rasht

Postal code

Approval date

empty

Ethics committee reference number

5012

Health conditions studied

1

Description of health condition studied

nasal polyposis

ICD-10 code

J33

ICD-10 code description

Nasal polyp

Primary outcomes

1

Description

recurrence of nasal poliposis

Timepoint

one week- one month- monthly up to 3 months

Method of measurement

clinical examination- diagnostic endoscopic

Secondary outcomes

1

Description

respiratory problems

Timepoint

end of 4th month

Method of measurement

questionnaire

Intervention groups

1

Description

amphotericin B solution

Category

Treatment - Drugs

2

Description

nasal Beclometazone Spray

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Shadman Nemati
Street address
City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Research Vice
Street address
Rasht- Namjou st
City
Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan 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
Guilan University of medical sciences
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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