

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation the efficacy of non-liposomal amphotericin B in the treatment of chronic sinusitis

Protocol summary

Study aim

Evaluation the efficacy of topical non-liposomal amphotericin B in the treatment of chronic sinusitis

Design

Double-blind Clinical trial with control group and parallel , phase 2-3 on 80 patients, by simple randomization method using closed door envelope

Settings and conduct

This double blind randomized clinical trial (participants and analyzers would blinded) is performed in the ENT ward of Ghaem Hospital in Mashhad on 80 patients with chronic sinusitis who were candidates for endoscopic surgery according to the doctor's diagnosis. Eligible patients are divided into control and intervention groups after obtaining consent. In the intervention group, in addition to routine treatment with amphotericin B solution, and in the control group with normal saline for nasal lavage twice a day for one month will be used and finally the results would be entered into SPSS software and analyzed.

Participants/Inclusion and exclusion criteria

Patients with chronic sinusitis who, according to the physician, were candidates for endoscopic surgery and would fully satisfied entering the project and had no history of surgery or use of antifungal antibiotics in the past month and did not have underlying diseases such as granulomatosis or kidney disease.

Intervention groups

In the intervention group, 40 patients with chronic sinusitis in addition to routine treatment would use amphotericin B solution for nasal lavage twice a day for a month and in the control group of 40 patients in addition to routine treatment would Use normal saline solution twice a day for a month to rinse the nose.

Main outcome variables

Clinical status of the patient based on Land Criteria and status of polyps based on endoscopic findings before and after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N42**

Registration date: **2021-09-27, 1400/07/05**

Registration timing: **prospective**

Last update: **2021-09-27, 1400/07/05**

Update count: **0**

Registration date

2021-09-27, 1400/07/05

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of non-liposomal amphotericin B in the treatment of chronic sinusitis

Public title

The effect of amphotericin B on sinusitis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic sinusitis with polyposis Candidate for sinus endoscopy surgery Conscious consent to participate in the study

Exclusion criteria:

Co-occurrence of systemic diseases such as diabetes, chronic renal failure, malignancies, cystic fibrosis, or granulomatous diseases Being pregnant Breastfeeding Have no history of surgery in the last month Have no history of taking antifungal antibiotics in the past month

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects and those evaluating the outcome will be unaware of the intervention and control groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Science

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9117699199

Approval date

2019-08-13, 1398/05/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.448

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

Chronic sinusitis and polyposis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis, unspecified

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

Clinical status

Timepoint

At the end of 4 weeks

Method of measurement

Land Score

2**Description**

Recurrence of polyps

Timepoint

At the end of 4 weeks

Method of measurement

Based on endoscopic criteria of the nose

Secondary outcomes

empty

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

Intervention group: In this group, 40 patients, in addition to routine treatment, use amphotericin B solution for rinsing the nose twice a day for a month.

Category

Treatment - Other

2

Description

Control group: In this group, in addition to routine treatment, 40 patients use normal saline solution for rinsing the nose twice a day for a month.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Nazanin Yousefi

Street address

Ghaem Hospital, Ahmad Abad AVE

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Email

Yousefin961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadreza Majidi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

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Mohammadreza Majidi

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available