

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Efficacy of Mupirocin Ointment into Nostril on polyposis recurrence Following Functional endoscopic sinus surgery (FESS) in Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

Protocol summary

Study aim

Investigating the effect of using mupirocin ointment into nostrils of chronic rhinosinusitis with nasal polyposis patients in reducing the recurrence of polyps after functional endoscopic sinus surgery

Design

Double-blind case-controlled clinical trial among 24 Caucasian patients with Chronic rhinosinusitis with nasal polyps (CRSwNP) who underwent sinus surgery between 2020-2021 and followed for 6 months

Settings and conduct

24 patients with Chronic Rhinosinusitis with Nasal Polyposis and a positive nostrils culture for Staphylococcus aureus who had been referred for sinus surgery to the Firoozgar general hospital and Rasool general Hospital, Tehran, Iran, between 2020-2022. The right nostril in each patient was determined as the intervention group (applying mupirocin ointment) and the left nostril as the control group (applying vitamin A ointment). Lund-Mackay radiological scores and Lund-Kennedy endoscopic scores were examined at the time of diagnosis and 6 months after ointment usage

Participants/Inclusion and exclusion criteria

Patients with Chronic Rhinosinusitis with nasal polyposis (CRSwNP) candidated for surgery with positive cultures from both nostrils for Staphylococcus aureus and their Lund Mackay (LM) and Lund Kennedy (LK) scores were almost same at both sides of the nose and sinuses were included; Nasal polyposis due to neoplasm, autoimmune diseases, Fungal sinusitis and ect except CRSwNP and patients with LM scores and LK scores were significantly different at both sides of the nose and sinuses were excluded

Intervention groups

In each patient the right nostril was determined as the intervention group (applying mupirocin ointment) and the left nostril as the control group (applying vitamin A

ointment)

Main outcome variables

Nasal nostril mupirocin ointment usage can not reduce polyp recurrence after sinus surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221013056165N1**

Registration date: **2024-05-05, 1403/02/16**

Registration timing: **retrospective**

Last update: **2024-05-05, 1403/02/16**

Update count: **0**

Registration date

2024-05-05, 1403/02/16

Registrant information

Name

Maryam Mohsenian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2670 7158

Email address

mmohsenian1987@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date
2021-09-22, 1400/06/31

Trial completion date
2022-03-21, 1401/01/01

Scientific title
Efficacy of Mupirocin Ointment into Nostril on polyposis recurrence Following Functional endoscopic sinus surgery (FESS) in Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

Public title
Mupirocin ointment effect on Polyposis recurrence after Sinus surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with CRSwNP candidate for surgery Lund-Mackay scores and Lund-kennedy scores were almost same at both sides of the nose and sinuses
Exclusion criteria:
Nasal polyposis due to neoplasm, autoimmune diseases, Fungal rhinosinusitis and ect except Chronic Rhinosinusitis with Nasal Polyposis Patients with Lund-Mackay and Lund-Kennedy scores were significantly different at both sides of the nose and sinuses

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **22**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 Positive culture for Staphylococcus aureus from nasal nostril swab samples from both sides of the nose
 Actual sample size reached: **24**
 More than 1 sample in each individual
 Actual sample size in each individual: **2**
 Positive culture for Staphylococcus aureus from nasal nostril swab samples from both sides of the nose

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants in the study did not know about the difference in the effect of the two types of ointment
Outcome evaluator was not aware of the study

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethnics committee of iran university of medical sciences

Street address

Research and Technology Vice-Chancellor, Central Headquarters Building, Iran University of Medical Sciences, Hemat Hwy. , Next to Milad tower

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-07-14, 1399/04/24

Ethics committee reference number

IR.IUMS.FMD.REC.1399.290

Health conditions studied

1

Description of health condition studied

Chronic Rhinosinusitis with Nasal Polyposis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Lund Mackay radiologic score

Timepoint

At the beginning of the study (before the start of the intervention), 6 months after using the ointment

Method of measurement

Lund Mackay radiologic scoring system

2

Description

Lund Kennedy endoscopic score

Timepoint

At the beginning of the study (before the start of the intervention), 6 months after using the ointment

Method of measurement

Lund Kennedy endoscopic scoring system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mupirocin-Najo 2%, topical ointment - made by Iran Najo pharmaceutical company, Tehran, Iran- was prescribed twice daily for six months from the time of primary surgery until the follow-up endoscopy into the right nostril

Category

Treatment - Drugs

2

Description

Control group: Xerovit (vitamin A), sterile ophthalmic ointment 25000 IU -made by Sina Darou Laboratories Company, Tehran, Iran- was prescribed twice daily for six months from the time of primary surgery until the follow-up endoscopy into the left nostril

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Maryam Mohsenian

Street address

Rasoul akram Hospital., Niayesh St., Sattarkhan St.

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2

Recruitment center

Name of recruitment center

Firrozgar hospital

Full name of responsible person

Maryam Mohsenian

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Firrozgar hospital., Beh afarin St., karimkhan zand Ave., Valiasr Sq.

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firoozgarhospital1@gmail.com

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<http://firoozgar.iums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

5th floor of the central headquarters., Next to Milad tower., Hemat Hwy.

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info@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Mohsenian

Position

Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Full name of responsible person
Maryam Mohsenian

Position
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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying participants

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

By citing the source, any analysis and use of the data is allowed

From where data/document is obtainable

Maryam Mohsenian Cellphone No: 0098 9124358854
Mail: mmohsenian1987@gmail.com

What processes are involved for a request to access data/document

First, the researcher's position in academic and scientific institutions is confirmed, then the data is sent to the individual within a month

Comments