Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Mupirocin Ointment into Nostril on polyposis reccurence 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 reccurence 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 reccurence 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.
City
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1445613131
Phone
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Email
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2

Recruitment center
Name of recruitment center
Firrozgar hospital
Full name of responsible person
Maryam Mohsenian
Street address
Firoozgar hospital., Beh afarin St., karimkhan zand Ave., Valiasr Sq.
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Email
firoozgarhospital1@gmail.com
Web page address
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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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1449614535
Phone
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Email
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 updating data

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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