Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of topical mitomycin in patients with relapsed nasal polyposis

Protocol summary

Study aim
The effect of topical mitomycin in patients with relapsed nasal polyposis
Design
A randomised, unblinded, parallel clinical trial with a control group; 3rd phase on 40 patients; An external site - Sealed Envelope - has been used for randomisation.
Settings and conduct
This study is a clinical trial that will be performed on patients aged 16 to 60 y/o with recurrent nasal polyposis after endoscopic sinus surgery who referred to Kashan Matini Hospital from 2020/07/31 .All patients with polyposis have pan-sinusitis and bilateral involvement of nasal cavity are similar.
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1 Patients aged 16 to 60 years with recurrent nasal polyposis Exclusion criteria: 1 All patients with underlying disorders including cystic fibrosis, kartagener, respiratory ciliary mobility disorder 2 People with systemic diseases such as diabetes and high blood pressure
Intervention groups
During this study, at the end of surgery in a group in the nasal cavity of a cotton mesh impregnated with 1.5 cc of mitomycin 0.1 mg / ml in the opposite group, cotton soaked in 1.5 cc of normal saline was placed as a placebo for five minutes in the opening of the frontal sinus and inside the maxillary sinus and ethmoid and sphenoid.
Main outcome variables
Recurrence of nasal polyps

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200810048356N1**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **retrospective**
Last update: **2020-09-29, 1399/07/08**
Update count: **0**
Registration date
2020-09-29, 1399/07/08

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-31, 1399/05/10
Expected recruitment end date
2020-08-15, 1399/05/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of topical mitomycin in patients with relapsed nasal polyposis

Public title
Effect of mytomycin on relapsed nasal polyposis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Recurrence of nasal polyps after one or more surgery
Exclusion criteria:

People with systemic diseases such as diabetes and high blood pressure All patients with underlying disorders including cystic fibrosis, kartagener, respiratory ciliary mobility disorder

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with quadruple blocks was assigned to two groups. An external site - Sealed Envelope - has been used for randomisation. In this site using random numbers we assigned 40 numbers to two groups of A and B. Then , using the above list patients were referred to the assigned groups , respectively. For example, if in the mentioned list, the No.1 and 2 are in group A and the No. 3 is in group B, the first and the second patient will be in group A and the third patient will be in group B.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan Medical University

Street address

No. 5, Iman St., Bahonar Blvd., Moallem Blvd., Kashan

City

Kashan

Province

Isfehan

Postal code

8714869483

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.073

Health conditions studied

1

Description of health condition studied

Recurrence of nasal polyps

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The symptoms in the two groups of study will be determined and compared before surgery and one and six months after that, as the outcome of this clinical trial by questionnaire. Evaluation of the patient's clinical symptoms in this questionnaire that is based on Rhinosinusitis Symptom Inventory System will be made and scored before and after the treatment.

Timepoint

Before surgery and one and six months after that by questionnaire

Method of measurement

Questionnaire based on Rhinosinusitis Symptom Inventory System

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During this trial, at the end of surgery, in one group, cotton mesh impregnated with 1.5 cc of mitomycin 0.1 mg / ml is placing in the nasal cavity for 5 minutes. In this study, the Mitonco, product of KOREA UNITED PHARM Inc is using.

Category

Treatment - Drugs

2

Description

Control group: At the end of the surgery, cotton mesh impregnated with 1.5 cc of normal saline is placing in the frontal sinus and inside the maxillary, ethmoid and sphenoid sinus, for five minutes as a placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Matini hospital in kashan

Full name of responsible person
DR.Amirhosseinahsaniarani
Street address
No. 5 Iman St. 4, Bahonar Blvd Moallem Square,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
DR Amirhossein Ahsani Arani
Position
Assistant professor
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Person responsible for updating data

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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
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
This study will be published in the form of an article. Also, as a dissertation of the general practitioner in this study at Kashan University of Medical Sciences, colleagues will be informed
When the data will become available and for how long
After concluding and analyzing the data, access will be possible
To whom data/document is available
All researchers, students and colleagues
Under which criteria data/document could be used
Volunteer researchers on a similar project
From where data/document is obtainable
Kashan Matini Hospital
What processes are involved for a request to access data/document
Approval of Dr. Ahsani, principal researcher and ethics committee of Kashan University of Medical Sciences
Comments