

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Name

Amirhossein Ahsaniarani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5557 0331

Email address

ahsaniaraniamirhossein@kaums.ac.ir

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

Isfahan

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,

City

Kashan

Province

Isfahan

Postal code

8714869483

Phone

+98 31 5557 0331

Email

fatemeh.ffty@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Banafshe

Street address

Kashan Ravand Boulevard University of Medical Sciences

City

kashan

Province

Isfahan

Postal code

8714869483

Phone

+98 31 5554 0021

Email

fatemeh.ffty@gmail.com

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

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

No. 5 Iman 4 Bahonar Blvd. Moallem Square

City

Kashan

Province

Isfahan

Postal code

8714869483

Phone

+98 31 5557 0331

Email

fatemeh.ffty@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Amirhossein Ahsani Arani

Position

Assistant professor

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

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Dr Amirhossein Ahsani Arani

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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