

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Montelukast on Prevention of Nasal Polyps Recurrence Following Functional Endoscopic Sinus Surgery.

Protocol summary

Study aim

Determining the effect of Montelukast on the prevention of nasal polyp recurrence after endoscopic functional sinus surgery

Design

Clinical trial with an intervention group, phase 3, sample size 69, with a parallel group; One side blind, randomized using block randomization

Settings and conduct

This study is conducted in Razi Birjand Hospital, South Khorasan Province. 138 patients were randomly divided into two intervention groups, one or two (A-B). Questions related to the effectiveness of the intervention before and 6 weeks after the treatment will be asked and evaluated by the moderator.

Participants/Inclusion and exclusion criteria

Patients with chronic rhinosinusitis will be referred to the Otolaryngology Clinic of Razi Birjand Hospital in 2023. The inclusion criteria include: age over 18 years, taking medication regularly, consent to participate in the study, cooperation with the present research team, candidate for endoscopic sinus surgery. Exclusion criteria include: patients with exacerbation of recurrent acute rhinosinusitis, rhinosinusitis without polyposis, sinusitis associated with ciliary dyskinesia or sinusitis associated with cystic fibrosis.

Intervention groups

The intervention groups are as follows: Group A receiving Montelukast 10 mg once a day at night and Group B receiving a topical steroid such as fluticasone 0.1 mg twice a day, 50 micrograms each time.

Main outcome variables

Runny nose, improvement of symptoms compared to before taking the drug, clinical symptoms include: headache, nasal congestion, sinus pain, PND, pain around the eyes, pus in the nose, cough, runny nose and decreased sense of smell

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N16**

Registration date: **2023-02-08, 1401/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

Registration date

2023-02-08, 1401/11/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Montelukast on Prevention of Nasal Polyps Recurrence Following Functional Endoscopic Sinus Surgery.

Public title

The effect of Montelukast on the prevention of nasal polyp recurrence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Candidate for endoscopic sinus surgery Consent to participate in the study Cooperation with the present research team

Exclusion criteria:

History of allergy to prescribed medication for the patient presence of eye disease immunodeficiency disease allergic rhinitis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

The placement of people in each group will be randomized in a simple and blocked way, in one of the two groups A (receiver of Montelukast 10 mg tablets daily, one at night), intervention B (receiver of a topical steroid such as fluticasone 0.1 mg twice a day (50 micrograms each time) will be placed. In this way, first, various blocks of four are created on different cards (AABB, BBAA, ABAB, BABA, ABBA, BAAB). One of these blocks will be randomly selected and the patients will be divided into one of two groups A or B. Then randomization will be done for other patients as well.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome evaluator: The study administrator, without knowing the type of drug received, asks questions from the patients and records them in the relevant checklist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

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Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2022-06-20, 1401/03/30

Ethics committee reference number

IR.BUMS.REC.1401.136

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis

ICD-10 code

J31.0

ICD-10 code description

Chronic rhinitis

Primary outcomes

1

Description

Runny nose

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

2

Description

headache

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

3

Description

nasal congestion

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

4

Description

sinus pain

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

5

Description

pain around the eyes

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

6

Description

pus in the nose

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

7

Description

cough

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

8

Description

Decreased sense of smell Before and After Treatment.

Timepoint

Runny nose before and 6 weeks after treatment.

Method of measurement

By asking the patient.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group: Group A received Montelukast tablets 10 mg daily, once at night for 6 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group:

group B receiving a topical steroid such as fluticasone 0.1 mg twice a day, 50 micrograms each time for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Otorhinolaryngology Clinic, Razi Birjand Hospital

Full name of responsible person

Mahsa Mirzaee

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Birjand 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

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Person responsible for general inquiries

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available