Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Zabihullah Mohaghegh

Name of organization / entity

Country
Iran (Islamic Republic of)

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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
City
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
Street address
Otorhinolaryngology Clinic of Rzai Hospital , Ghafari Blvd, Birjand Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Mohammadreza Miri
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Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town
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9717811674
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research@bums.ac.ir
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

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaqiq

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Masoud Asghari

Position

Member of the Faculty

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

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Other areas of specialty/work

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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