Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect Sprays of fluocycan, boutsonide and mometazone in patients with nasal-sinus polyposis after sinus endoscopic surgery

Protocol summary

Study aim
Comparison of the effect of fluticasone spray and budesonide spray and mometasone spray in patients with nasal-sinus polyposis after endoscopic sinus surgery.

Design
Clinical trial with control group, with parallel group; double blind, randomized

Settings and conduct
This study is performed in Valiasr Hospital of Birjand, South Khorasan Province. 96 patients are randomly divided into three intervention groups one to three (A-C). Questions related to the effectiveness of the spray before and after treatment will be asked and evaluated by the ward nurse.

Participants/Inclusion and exclusion criteria
Inclusion criterion includes having informed consent. Exclusion criteria include: having allergic rhinitis, eye disease, known immunodeficiency disease, infectious symptoms including purulent discharge from the back of the throat and nose.

Intervention groups
The intervention groups are as follows: Group A received fluticasone nasal spray twice daily (50 micrograms per puff). Group B receive budsonide spray twice daily (50 micrograms per puff). Group C receive mometasone spray twice daily (50 micrograms per puff).

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: **IRCT20190618043934N7**
Registration date: **2020-08-04, 1399/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-04, 1399/05/14**
Update count: **0**

Registration date
2020-08-04, 1399/05/14

Registrant information

Name
Zabihullah Mohaghegh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-30, 1399/04/10

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect Sprays of fluocycan, boutsonide

and mometazone in patients with nasal-sinus polyposis after sinus endoscopic surgery

Public title
The effect of fluticasone, budesonide and mometasone on nasal polyposis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic rhinosinusitis with nasal polyps who have undergone sinus endoscopic surgery. Patients aged 15 to 70 years Having conscious satisfaction
Exclusion criteria:
Existence of eye disease Existence of known immunodeficiency disease Infectious symptoms include purulent discharge from the back of the throat and nose Having Allergic rhinitis
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
The placement of individuals in each group will be randomly simple and blocked, which will be in one of three groups A (fluticasone spray), intervention B (budsonide spray) or group C (mometasone spray). First, various triple blocks are created on different cards (ABC, CAB, CBA, BCA, BAC and ACB). One of these blocks is randomly selected and patients will be divided into one of three groups A, B or C. Then randomization is performed for other patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome Assessor: The ward nurse, without knowing the type of medication received, questions 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
Ghaffari Str
City
Birjand
Province
South Khorasan
Postal code
9717811674
Approval date
2020-07-13, 1399/04/23
Ethics committee reference number
IR.BUMS.REC.1399.166

Health conditions studied

1

Description of health condition studied
Nasal polyps
ICD-10 code
J33
ICD-10 code description
Nasal polyp

Primary outcomes

1

Description
Runny nose
Timepoint
runny nose before and After treatment.
Method of measurement
By asking the patient.

2

Description
headache
Timepoint
headache before and After treatment.
Method of measurement
By asking the patient.

3

Description
nasal congestion before and After treatment.
Timepoint
nasal congestion
Method of measurement
By asking the patient.

4

Description
sinus pain
Timepoint
sinus pain before and After treatment.

Method of measurement
By asking the patient.

5

Description
pain around the eyes
Timepoint
pain around the eyes before and After treatment.
Method of measurement
By asking the patient.

6

Description
pus in the nose
Timepoint
pus in the nose before and After treatment.
Method of measurement
By asking the patient.

7

Description
cough
Timepoint
cough before and After treatment.
Method of measurement
By asking the patient.

8

Description
Decreased sense of smell Before and After Treatment.
Timepoint
Decreased sense of Smell Before and After Treatment.
Method of measurement
By Asking The Patient.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Group A receiving fluticasone nasal spray twice a day, 0.1 mg (manufactured by Jaber Bin Hayan Pharmaceutical Company) for 4 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: Group B receiving Budesonide nasal spray twice a day, 0.1 mg (manufactured by Jaber Bin Hayan Pharmaceutical Company) for 4 weeks.
Category
Treatment - Drugs

3

Description
Intervention group 3: Group C receiving Mometasone nasal spray twice a day, 0.1 mg (manufactured by Jaber Bin Hayan Pharmaceutical Company) for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
ValieAsr Hospital
Full name of responsible person
Haniye Sadat Razavi
Street address
Ghaffari Str
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr. Tooba Kazemi
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Zabihullah Mohaghegh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no need to publish individual patient information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available