Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effect of Olopatadine nasal spray compared to Mometasone spray in the treatment of allergic rhinosinusitis cases refered to ENT clinic of Heshmatieh Hospital Sabzevar

Protocol summary

Study aim

Evaluation of the effect of olapatadine nasal spray in comparison with mometasone spray in the treatment of allergic rhinosinusitis

Design

A clinical trial study with two intervention groups, with parallel groups, double-blind, randomized, is performed on 100 patients. Balanced Block Randomization method is used for randomization.

Settings and conduct

This is an interventional study that will be performed on patients with allergic rhinosinusitis referred to the ENT clinic of Heshmatieh Hospital in Sabzevar from September 1, 2016. Patients are randomly assigned to the study groups based on the Balanced Block Randomization method. Symptoms of allergic rhinosinusitis in patients before the intervention are scored according to the SNOT22 questionnaire. Then, on the first, third and fourteenth day after starting treatment, patients will answer the SNOT22 questionnaire again.

Participants/Inclusion and exclusion criteria

Conditions of entry: age 18 to 60 years; Patients with confirmed allergic rhinosinusitis; Written consent to enter the study; Patient cooperation during the study; Timely and correct use of medication; Absence of abnormal nasal anatomy; Absence of severe nasal congestion due to polyps, other lesions and obstructive masses; Absence of respiratory infections; Non-smokers; Absence of upper and lower lung diseases affecting the final consumption or absorption of the nose; Absence of symptoms of systemic diseases Conditions of non-entry: individuals known for not responding to antihistamines; Known intolerance or sensitivity to drugs

Intervention groups

Intervention group 1: administration of Olopatadine nasal spray 0.6% every 12 hours (made by Daroo Pakhsh Tehran) Intervention group 2: administration of Mometasone 50 mg nasal spray every 6 hours (made by Caspian Drug Company of Rasht)

Main outcome variables

Response to treatment in the studied groups, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200727048222N1**
Registration date: **2020-09-26, 1399/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-26, 1399/07/05**
Update count: **0**

Registration date

2020-09-26, 1399/07/05

Registrant information

Name

Ehsan Ebrahimzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4424 3658

Email address

ehsanebrahimzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-21, 1399/05/31

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Olopatadine nasal spray compared to Mometasone spray in the treatment of allergic rhinosinusitis cases refered to ENT clinic of Heshmatieh Hospital Sabzevar

Public title
Comparison of the effect of Olapatadine nasal spray with Mometasone spray in the treatment of allergic rhinosinusitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 60 years Patients with confirmed allergic rhinosinusitis Written consent to enter the study Patient cooperation during the study Timely and correct use of medication by asking the patient Absence of abnormal nasal anatomy Absence of severe nasal congestion due to polyps, other lesions and obstructive masses Absence of respiratory infections Non-smokers Absence of upper and lower lung diseases affecting the final consumption or absorption of the nose Absence of symptoms of systemic diseases

Exclusion criteria:
People known for not responding to antihistamines Known intolerance or sensitivity to drugs

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, a simple block method will be used. The individual randomization unit and the randomization tool are sealed drug packages that are completely similar in shape and the patient and the project operator are not aware of the contents of the packages. The allocation of samples in the study will be based on a random sequence provided by the statistical consultant using statistical software. The sequence used will be quadruple blocks. Random allocation software is also a tool for generating random block sequences.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind each patient, it is numbered by the supervisor and recorded in a notebook; For example, patient No. 1 receives box A medicine and patient number 2 receives box B medicine. While the researcher and patients do not know the content of the drug in the envelopes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences

Street address
Memarzadeh Alley, Enghelab St 5., Najar Abad Blvd

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Approval date
2020-06-20, 1399/03/31

Ethics committee reference number
IR.MEDSAB.REC.1399.074

Health conditions studied

1

Description of health condition studied
Allergic rhinosinusitis

ICD-10 code
J99

ICD-10 code description
Allergic rhinosinusitis

Primary outcomes

1

Description
Response to treatment of olapatadine and mometasone spray groups

Timepoint
Before the intervention and on days 1, 3 and week 2 after starting the medication

Method of measurement
Sino Nasal Outcome Test 22 questionnaire

2

Description
Satisfaction of patients receiving olapatadine and mometasone spray groups
Timepoint
2 weeks After starting the intervention
Method of measurement
5 point scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Olopatadine nasal spray 0.6% every 12 hours (made by Daroo Pakhsh Tehran)
Category
Treatment - Drugs

2

Description
Intervention group: Mometasone 50 mg nasal spray every 6 hours (made by Caspian Drug Company of Rasht)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sabzevar Heshmatieh Hospital
Full name of responsible person
Mahmoud Hekmat Shoar
Street address
Asadabadi St., Central Organization of University of Medical Sciences
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617213112
Phone
+98 51 4401 8484
Fax
+98 51 4401 1000
Email
dr.mhekmat@ymail.com
Web page address
http://www.medsab.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mahmoud Hekmat Shoar
Street address
Asadabadi St., Central Organization of University of Medical Sciences
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617213112
Phone
+98 51 4401 1000
Fax
+98 51 4401 8484
Email
dr.mhekmat@ymail.com
Web page address
http://www.medsab.ac.ir/
Grant name
Vice Chancellor for Research, Sabzevar University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Ehsan Ebrahimzadeh
Position
General medical student
Latest degree
A Level or less
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Memarzadeh St., 5th Enghelab Street,Najarabad Boulevard., Sabzevar Town
City
Sabzevar

Province
Razavi Khorasan
Postal code
9617213112
Phone
+98 51 4424 3658
Fax
Email
ehsanebrahimzadeh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Ehsan Ebrahimzadeh
Position
General medical student
Latest degree
A Level or less
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Memarzadeh St., 5th Enghelab Street,Najarabad Boulevard., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617213112
Phone
+98 51 4424 3658
Fax
Email
ehsanebrahimzadeh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Ehsan Ebrahimzadeh
Position
General medical student
Latest degree
A Level or less
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Memarzadeh St., 5th Enghelab Street,Najarabad Boulevard., Sabzevar Town
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Province
Razavi Khorasan
Postal code
9617213112
Phone
+98 51 4424 3658
Fax
Email
ehsanebrahimzadeh@yahoo.com

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
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