

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 referred to ENT clinic of Heshmatieh Hospital Sabzevar

Protocol summary

Study aim

Evaluation of the effect of olopatadine 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 referred 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

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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

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Postal code

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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

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

Sabzevar University of Medical Sciences

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

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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

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