Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the efficacy of a combination of Mometasone and Olopatadine sprays versus Mometasone spray in children with allergic rhinitis

Protocol summary

Study aim

Comparing the effectiveness of the combination of mometasone and olopatadine sprays with mometasone spray in children with allergic rhinitis

Design

Phase 3, two arms parallel group randomized trial, triple blinded, 80 children aged 6-12, using a block randomization method to allocate the patients into two groups. Randomization process will be conducted using random allocation software.

Settings and conduct

Children referred to allergy clinics of Urmia University of Medical Sciences. The first group will receive two mometasone sprays and Allanthin, administered twice daily at doses of 25 and 665 micrograms, respectively. The second group will receive mometasone spray alone at a dose of 25 micrograms every 12 hours. The sprays will be provided off-label and in identical containers to blind the patients. assess the patients on the 7th, 1st, and 14th days after the study begins through a phone call.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of allergic rhinitis by a clinical allergist; age 6-12 years old and written consent from parents. Exclusion criteria: a known history of nasal polyps, other significant abnormalities in the respiratory system; structural abnormalities of the nose; septum deviation; chronic, acute, or severe sinusitis or postpharyngeal discharge and drug-induced rhinitis and active pulmonary disorder or infection or upper respiratory tract or sinus infection within the past 14 days.

Intervention groups

The first group consisted of patients who received two sprays of mometasone and allanthin, with doses of 25 and 665 micrograms, respectively, twice daily. The second group included patients who received mometasone spray alone at a dose of 25 micrograms every 12 hours.

Main outcome variables

Rhinoconjunictivits quality of life and TNSS Questionnaire (Nasal congestion, nasal secretions, nasal itching, sneezing and sleep problems)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150426021944N5**
Registration date: **2024-05-31, 1403/03/11**
Registration timing: **prospective**

Last update: **2024-05-31, 1403/03/11**
Update count: **0**

Registration date

2024-05-31, 1403/03/11

Registrant information

Name

Hamidreza Houshmand

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-19, 1403/03/30

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of a combination of Mometasone and Olopatadine sprays versus Mometasone spray in children with allergic rhinitis

Public title

Comparing the efficacy of a combination of Mometasone and Olopatadine sprays versus Mometasone spray in children with allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Allergic rhinitis diagnosis by a clinical allergist collaborating in the project (based on the presence of clinical symptoms such as sneezing, nasal congestion, nasal secretions, and nasal itching or based on a positive prick test or a positive IgE specific to allergens) Age 6-12 years old Obtaining written informed consent from parents

Exclusion criteria:

Known history of nasal polyps, other clinically significant respiratory system abnormalities Structural abnormalities of the nose Septum deviation Chronic, acute, or significant sinusitis or post-nasal drip (PND) Drug-induced rhinitis; active pulmonary disorder or infection (e.g., bronchitis, pneumonia, or influenza) Upper respiratory tract or sinus infection within the past 14 days Other important clinical abnormalities of the respiratory system

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method will be utilized to assign participants to two groups. The block size will be set at 8, initially listing all possible combinations of AAAABBBBB with a unique code for each. Subsequently, 10 blocks will be randomly selected based on a sample size of n=80, and participants will be allocated according to the order of these chosen blocks. The complete randomization procedure will be conducted using random allocation software overseen by an epidemiology expert.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding will be three-way. The drugs (spray) will be prepared and given to the patients in uniform and identical containers without labels. The list of patients will be listed based on secret codes, which will be available to the researcher, evaluator, and statistical analyzer. Only one nurse outside of the research team will have access to the list to take action on complications.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Science

Street address

Urmia University of Medical Sciences, Orzhans Alley, Resalat St. ,Urmia , Iran

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West Azarbaijan

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Approval date

2023-11-19, 1402/08/28

Ethics committee reference number

IR.UMSU.REC.1402.254

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30

ICD-10 code description

Vasomotor and allergic rhinitis

Primary outcomes

1

Description

Quality of life

Timepoint

Days 7, 1 and 14 after intervention

Method of measurement

Pediatric Rhino Conjunctivitis Quality of Life Questionaire(PRQLQ)

Secondary outcomes

1

Description

TNSS questionnaire

Timepoint

Days 7, 1 and 14 after the intervention

Method of measurement

TNSS questionnaire(Total Nasal Symptom Score: TNSS)

Intervention groups

1

Description

Intervention group: Patients receiving two sprays of mometasone and allanthin with doses of 25 micrograms and 665 micrograms twice a day (every 12 hours)

Category

Treatment - Drugs

2

Description

Control group: Patients receiving mometasone spray alone at a dose of 25 mcg every 12 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia University of Medical Sciences

Full name of responsible person

Hamidreza Houshmand

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Urmia 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

Oroumia University of Medical Sciences

Full name of responsible person

Hamidreza Hoshmand

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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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
According to the ethical considerations and policies of the institution (University of Medical Sciences), there will be no sharing of data and it is subject to obtaining the necessary permits.
Study Protocol
No - There is not 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
Not applicable