

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effects of nasal lavage with normal saline in the treatment of allergic rhinitis in children 6 to 12 years old refers to allergic clinics of Urmia university of medical science

Protocol summary

Study aim

Determining the effects of washing the nose with normal saline in the treatment of allergic rhinitis in children 6 to 12

Design

Randomized Clinical trial with control group, two parallel groups, children with allergic rhinitis aged 12-6 years divided two groups by block randomization method using Random allocation software

Settings and conduct

A study on children with allergic rhinitis referred to Urmia University of Medical Sciences' allergy clinics will be conducted, which will be randomly assigned to one of the two groups. The control group receives standard treatment (including oral antihistamine (1citrizine every 2 hours) and intranasal corticosteroids (Mometasone) every 12 hours), and the second group, in addition to standard treatment, nasal washes 4 times a day with a saline-soluble .65 % solution. Signs such as sneezing, nasal runaway, nasal itching, nasal obstruction, itching palate, eye symptoms, and disruption to the daily activity and sleep of the patients will be collected before starting treatment and at intervals of one and three months using the RQLQ questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children with allergic rhinitis aged 12-6 years Parental Informed consent to participate in the study Exclusion criteria: Non-allergic rhinitis, adenoid enlargement, infectious rhinitis, Concha Bollusa, intranasal meningocele, nasal polyp

Intervention groups

The control group receives standard treatment (including oral antihistamine (1citrizine every 2 hours) and intranasal corticosteroids (Mometasone) every 12 hours), and the second group, in addition to standard treatment, nasal washes 4 times a day with a saline-soluble .65 % solution.

Main outcome variables

Sneezing, nasal runaway, nasal itching, nasal obstruction, itching palate, eye symptoms, and disruption to the daily activity and sleep using the RQLQ questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150426021944N4**

Registration date: **2023-04-08, 1402/01/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-08, 1402/01/19**

Update count: **0**

Registration date

2023-04-08, 1402/01/19

Registrant information

Name

Hamidreza Houshmand

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 7288

Email address

hamidreza.houshmd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of nasal lavage with normal saline in the treatment of allergic rhinitis in children 6 to 12 years old refers to allergic clinics of Urmia university of medical science

Public title
Evaluation of the effects of nasal lavage with normal saline in the treatment of allergic rhinitis in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Allergic rhinitis Age 6-12 year Parents consent to participate in the study
Exclusion criteria:
Enlargement of Adenoids Infectious rhinitis Concha Bollusa Myelomeningocele Nasal polyps

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of individuals into the two groups will be used by the blocked randomization method. For this method, blocks will first be created with a size equal to 6 and a combination of AAA BBB and then all possible combinations will be created and listed, and then each combination of a data assignment code will be created. It will, according to the sample size (n=96) and the block size (6), randomly select 16 blocks, all of these steps will be performed under the supervision of an epidemiologist consultant using Random Allocation Software.

Blinding (investigator's opinion)
Not blinded

Blinding description

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 Sciences

Street address

Vice Chancellor for Research, UMSU Central Site, Orjhans Street, Resalat Blvd, Urmia ,Iran

City

ارومیه

Province

West Azarbaijan

Postal code

5714783734

Approval date

2023-01-07, 1401/10/17

Ethics committee reference number

IR.UMSU.REC.1401.354

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

PRQLQ (The Pediatric Rhinoconjunctivitis Quality of Life Questionnaire)

Timepoint

Before, one and three month after intervention

Method of measurement

PRQLQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receives standard treatment (including oral antihistamine (1citrizine every 2 hours) and intranasal corticosteroids (mometasone) every 12 hours), and nasal wash 4 times a day with a saline-soluble .65 % solution

Category

Treatment - Drugs

2

Description

Control group: receives standard treatment (including oral antihistamine (1citrizine every 2 hours) and intranasal corticosteroids (mometasone) every 12 hours)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergi clinic of Urmia university of medical sciences

Full name of responsible person

Hamid reza Hoshmand

Street address

Kasahni Ave. Motahhari Hospital

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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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

Oroumia 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

Hanid-Reza Hoshmand

Position

Assosiate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Pediatrics

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Email

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

Not applicable

Data Dictionary

Not applicable