Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison between nasal mucosiliary clearance in children with moderate to severe allergic rhinitis in two groups treated with or without normal saline irrigation

Protocol summary

Study aim
Comparison of nasal mucociliary clearance in children with moderate and severe allergic rhinitis treated with and without normal saline irrigation

Design
This study is a clinical trial with a control group, with crossover groups , without blinding, with block randomization. It will be done on 108 children aged 6 to 12 with a history of seasonal allergic rhinitis. Random Allocation Software will be used for randomization.

Settings and conduct
Nasal cleansing test will be measured before and 4 weeks after nasal washing in all patients. 54 children will be taught to wash their nose regularly 3 times a day with normal saline solution for 6 weeks, and 54 patients will not wash their nose with normal saline.Also , the patients of both groups will be treated with oral antihistamine drugs at the same time, and the amount of antihistamine drug consumption will be collected at the end of each week.This study is done in Ayatollah Motahari hospital of urmia in 1402.

Participants/Inclusion and exclusion criteria
Entrance: 1) 6-12 year old children with moderate and severe allergic rhinitis Exit: 1) Children with non-allergic rhinitis 2) Children with adenoide hyperplasia,bening and malignant tumors,pemphigus,nasal foreign body or nasal polyp 3) Any trauma during the review period

Intervention groups
Nasal cleansing test will be measured before and 4 weeks after nasal washing in all patients. 54 children will be taught to wash their nose regularly 3 times a day with normal saline solution for 6 weeks, and 54 patients will not wash their nose with normal saline.Also , the patients of both groups will be treated with oral antihistamine drugs at the same time, and the amount of antihistamine drug consumption will be collected at the end of each week.

Main outcome variables
Mucociliary clearance time,Quality of life of children with allergic rhinitis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231016059741N1**
Registration date: **2023-11-06, 1402/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-06, 1402/08/15**
Update count: **0**

Registration date
2023-11-06, 1402/08/15

Registrant information
Name
Maryam Dabbagh Shahir
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3224 8760
Email address
m4ry4m.dsh@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-09-23, 1402/07/01
Expected recruitment end date
2024-03-19, 1402/12/29
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between nasal mucosiliary clearance in children with moderate to severe allergic rhinitis in two groups treated with or without normal saline irrigation

Public title
Comparison between nasal mucosiliary clearance in children with moderate to severe allergic rhinitis in two groups treated with or without normal saline irrigation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
6-12 year old children with moderate and severe allergic rhinitis
Exclusion criteria:
Children with adenoide hyperplasia,bening and malignant tumors,pemphigus,nasal foreign body or nasal polyp Any trauma during the review period
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: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization will be by the block randomization method,so that first the blocks will be listed in the size of 6 of combination(AAABBB) and a code will be assigned to each one, and then according to the sample size (108) and Blocks(6) in the number of 17 blocks will be selected using simple randomization method.All this process will be done using Random Allocation Software under the supervision of an epidemiologist.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
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
Gavam 6 apartment, Emdad 1 Alley ,Modiriyat Ave.,Rahnamayi square., Rahnamayi Ave
City
Urmia
Province
West Azarbaijan
Postal code
5714781795
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.UMSU.REC.1402.052

Health conditions studied

1

Description of health condition studied
Allergic rhinitis
ICD-10 code
J00
ICD-10 code description
Acute nasopharyngitis [common cold]

Primary outcomes

1

Description
Mucociliary Clearance Time
Timepoint
Before and 4 weeks after washing the nose with normal saline
Method of measurement
Minute

Secondary outcomes

1

Description
Quality of life of children with allergic rhinitis
Timepoint
Before and 4 weeks after washing the nose with normal saline
Method of measurement
According to the patients file

Intervention groups

1

Description
Intervention group:Nasal cleansing test will be measured before and 4 weeks after nasal washing in all patients.

54 children will be taught to wash their nose regularly 3 times a day with normal saline solution for 6 weeks .Also , the patients will be treated with oral antihistamine drugs , and the amount of antihistamine drug consumption will be collected at the end of each week.

Category

Diagnosis

2

Description

Control group:Nasal cleansing test will be measured before and 4 weeks after nasal washing in all patients.54 patients will not wash their nose with normal saline.Also , the patients of will be treated with oral antihistamine drugs, and the amount of antihistamine drug consumption will be collected at the end of each week.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Motahari hospital of Urmia

Full name of responsible person

Maryam Dabbagh Shahir

Street address

Kashani Ave., Ayatollah Motahari hospital

City

Urmia

Province

West Azarbaijan

Postal code

5714781795

Phone

+98 44 3224 8760

Email

M4ry4m.mdsh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Maryam Dabbagh Shahir

Street address

Gavam 6 apartment, Emdad 1 Alley ,Modiriyat Ave.,Rahnamayi square., Rahnamayi Ave

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Email

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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

Maryam Dabbagh Shahir

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
Begining of the access period 6 months after the publication of the study results(since 1403)
To whom data/document is available
The data will be accessible to everyone.
Under which criteria data/document could be used
The data will be accessible to everyone.
From where data/document is obtainable
The data can be received through the email registered here in the name of Maryam Dabbagh Shahir. M4ry4m.mdsh@gmail.com
What processes are involved for a request to access data/document
After receiving the email ,one or two weeks later, they will receive the data files.
Comments