

# 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 adenoid hyperplasia, benign 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**

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**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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**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

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**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**

Maryam Dabbagh Shahir

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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**