

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of montelukast with the usual dose of twice as much neotadine with intranasal mometasone in allergic rhinitis

Protocol summary

Study aim

Comparison of the effect of montelukast with the usual dose of twice as much neotadine with intranasal mometasone in allergic rhinitis

Design

The statistical population will be determined from patients referred to Bahrami Hospital. The sample size for each group was 15 people and a total of 60 people. The study groups include the first group of Neotadine once a day, the second group of Neotadine twice a day, the third group of Montelukast and the fourth group of Neotadine together with Montelukast. This is a phase 3 clinical trial.

Settings and conduct

Patients suffering from allergic rhinitis are referred to Bahrami Hospital in Tehran. This study is an interventional study

Participants/Inclusion and exclusion criteria

inclusion criteria : Moderate to severe allergic rhinitis
Age over 6 Having informed consent to enter the study
Exclusion criteria: Adenoid infection, asthma and hypertrophy Patient age under 6 years

Intervention groups

The first group of patients will be treated by nasal spray with mometasone at a dose of 100 micrograms (two puffs per nose) daily for 8 weeks with 5 mg des loratadine tablets every night for 8 weeks by a treatment specialist. Patients in the second group will be treated with mometasone nasal spray at a dose of 100 micrograms (two puffs per nose) daily for 8 weeks with 5 mg des loratadine (neotadine) tablets twice daily for 8 weeks by a treatment specialist. Patients in the third group will be treated with mometasone nasal spray at a dose of 100 micrograms (two puffs per nose) daily for 8 weeks along with 5 mg oral Montelukast tablets daily for two months

Main outcome variables

nasal congestion score

General information

Reason for update

Acronym

TMNS

IRCT registration information

IRCT registration number: **IRCT20211205053277N1**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Niloufar Ghanbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7781 7104

Email address

niloufargh67@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-02, 1402/02/12

Expected recruitment end date

2023-11-03, 1402/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of montelukast with the usual dose of twice as much neotadine with intranasal mometasone in allergic rhinitis

Public title

Evaluation of the effect of Montelukast in allergic rhinitis, Evaluation of the effect of neotadine in the treatment of allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having moderate to severe allergic rhinitis over 6 years of age having informed consent

Exclusion criteria:

Asthma infection and adenoid hypertrophy Patients with chronic diseases Antihistamine use during the last 1 month Systemic or topical corticosteroids History of neotadine allergy

Age

From **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were equally assigned to 4 groups using the permuted block method. In this way, each treatment group was assigned a code (the codes are A for the group receiving neotadine once a day, B for receiving neotadine twice a day, C for receiving montelukast and D for the group receiving neotadine and Montelukast). Then, a random number from 1 to 24 was assigned to different states of the blocks (ABCD, ABDC, ACDB,...), which were 24 states in total. After that, using the Random Sequence Generator software, random numbers were obtained and the order of the blocks in a list was determined. The blocks and numbers are as follows: ABCD for number 1, ABDC for number 2, ACBD for number 3, ACDB for number 4, ADBC for number 5, ADCB for number 6, BACD for number 7, BADC for number 8, BCAD for number 9, BCDA for number 10, BDAC for number 11, DBAC for number 12, BDCA for number 13, CABD for number 14, CADB for number 15, CDAB for number 16, CDBA for number 17, CBAD for number 18, CBDA for number 19, DABC for number 20, DACB for number 21, DCAB for number 22, DCBA for number 23, DBCA for number 24,((It should be noted that this list is predetermined and after the sample size is determined, the allocation will be done up to the fifteenth block of 4 according to the number of samples in each group. In this way, 15 people will be included in each group.)

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**

national system of ethics in biomedical research

Street address

Bahrami hospital , Ansaralhossein ave , south Sabalan , Tehran

City

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Province

Tehran

Postal code

1641744991

Approval date

2022-04-23, 1401/02/03

Ethics committee reference number

IR.TUMS.CHMC.REC.1401.033

Health conditions studied**1****Description of health condition studied**

allergic rhinitis

ICD-10 code

J30.89

ICD-10 code description

Other allergic rhinitis

Primary outcomes**1****Description**

Nasal symptom score

Timepoint

before treatment intervention and two months after treatment

Method of measurement

Nasal symptom scoring table

Secondary outcomes

empty

Intervention groups

1

Description

The patients in the first group will be treated by mometasone nasal spray with a dose of 100 micrograms (two puffs in each nose) daily for 8 weeks along with 5 mg desloratadine tablets every night for 8 weeks by a specialist.

Category

Treatment - Drugs

2

Description

Patients in the second group will be treated by mometasone nasal spray with a dose of 100 micrograms (two puffs in each nose) daily for 8 weeks along with 5 mg desloratadine (Neotadine) 1 tablet twice a day for 8 weeks by a specialist.

Category

Treatment - Drugs

3

Description

Patients in the third group will be treated with mometasone nasal spray at a dose of 100 micrograms (two puffs in each nose) daily for 8 weeks along with oral Montelukast tablets 5 mg daily for two months.

Category

Treatment - Drugs

4

Description

Patients in the fourth group will be treated with mometasone nasal spray at a dose of 100 micrograms (two puffs in each nostril) daily for 8 weeks, along with 5 mg oral Montelukast tablets and 1 desloratadine tablet for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami hospital

Full name of responsible person

Dr Alireza Shafii , Dr Niloufar Ghanbari

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South Sabalan , Ansaralhossein ave

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niloufargh67@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr fotoohi

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Keshavarz blvd , Ghods st . Central organization of Tehran University of Medical science

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tums_edu@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran University of Medical Science

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Niloufar Ghanbari

Position

Assistant Professor of Tehran University of Medical Science

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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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

The informed consent form and data analysis spss file will be shared.

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

The data will be available to academic and scientific institutions

Under which criteria data/document could be used

In order to be used in scientific articles and the optimal use of drugs in the course of treatment

From where data/document is obtainable

Refer to Bahrami Hospital and the people whose names are given in this plan

What processes are involved for a request to access data/document

The people named in this plan should be emailed as information will be available as soon as possible

Comments

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