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)

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+98 21 7781 7104

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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 , Ansaralhosein ave , south Sabalan , Tehran

City
tehran

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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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Tehran University of Medical Scince
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
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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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