

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the effectiveness of intranasal budesonide, oral montelukast and their combination in patients with allergic rhinitis

Protocol summary

Study aim

Determination and comparison of the effectiveness of intranasal budesonide, oral montelukast and their combination in patients with allergic rhinitis

Design

Three parallel group randomized trial, phase 2-3 on 135 patients. Random allocation software was used for randomization.

Settings and conduct

This study will be performed on patients referred to the ENT clinic of hospitals affiliated to Isfahan University of Medical Sciences with the criteria of allergic rhinitis in the SFAR questionnaire. Individuals are randomly divided into three groups: treatment with budesonide nasal spray, treatment with montelukast tablets, and combination therapy. All patients before, 3 weeks, 6 weeks and 12 weeks after starting treatment are evaluated and compared in terms of symptom severity by VAS and SNOT22 questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having allergic rhinitis and age over 15 years; Exclusion criteria: smoking, pregnancy, asthma, nasal polyps, severe nasal deviation, nasal tumor or mass, sinusitis, receiving any treatment for allergic rhinitis within a week before admission, severe underlying disease, and having Churg-Strauss

Intervention groups

A group treated with intranasal budesonide spray (1 puff of spray 64 micrograms per nose, morning and evening; a total of 256 micrograms per day); The other group was treated with montelukast tablets (1 tablet of montelukast 10 mg daily, in the evening) and the last group received combination therapy with budesonide spray (1 puff of spray 64 micrograms per nose, in the morning only; a total of 128 micrograms per day). In addition, they will receive montelukast tablets (1 montelukast tablet 10 mg in the evening).

Main outcome variables

Runny nose score, Sneezing score, Nasal congestion

score, Nasal itching score, Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N41**

Registration date: **2020-11-01, 1399/08/11**

Registration timing: **prospective**

Last update: **2020-11-01, 1399/08/11**

Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-05-15, 1400/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of intranasal budesonide, oral montelukast and their combination in patients with allergic rhinitis

Public title

Effect of budesonide, montelukast and their combination in allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having allergic rhinitis Age over 15 years

Exclusion criteria:

smoking Pregnancy Asthma Nasal polyps Severe nasal deviation Nasal tumor or mass Sinusitis Get any treatment for allergic rhinitis within a week before the visit Existence of severe underlying disease Having Churg-Strauss

Age

From 15 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 135

Randomization (investigator's opinion)

Randomized

Randomization description

Patients included in the study are randomly assigned into three groups using Random allocation computer software with the simple method.

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 Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar Jarib st, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

IR.MUI.MED.REC.1399.596

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**

Runny nose score

Timepoint

Before intervention, 3 weeks, 6 weeks and 12 weeks after treatment

Method of measurement

Visual Analogue Scale and Sino-nasal Outcome Test questionnaires

2**Description**

Sneezing score

Timepoint

Before intervention, 3 weeks, 6 weeks and 12 weeks after treatment

Method of measurement

Visual Analogue Scale and Sino-nasal Outcome Test questionnaires

3**Description**

Nasal congestion score

Timepoint

Before intervention, 3 weeks, 6 weeks and 12 weeks after treatment

Method of measurement

Visual Analogue Scale and Sino-nasal Outcome Test questionnaires

4**Description**

Itchy nose score

Timepoint

Before intervention, 3 weeks, 6 weeks and 12 weeks after treatment

Method of measurement

Visual Analogue Scale and Sino-nasal Outcome Test questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: treated with budesonide nasal spray by Jaber Ibn Hayyan Company (1 puff of spray 64 micrograms per nose, morning and evening; a total of 256 micrograms per day) for 3 months

Category

Treatment - Drugs

2

Description

Second intervention group: treated with montelukast tablets produced by Tehran Daru company (1 montelukast tablet 10 mg in the evening) for 3 months

Category

Treatment - Drugs

3

Description

Third intervention group: under combination treatment with budesonide spray by Jaber Ibn Hayyan (1 puff of spray 64 micrograms per nose, only in the morning; a total of 128 micrograms per day) plus montelukast tablets produced by Tehran Daroo Company (1 montelukast tablets 10 mg in the evening) for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Ahmad Rezaeian

Street address

Al-Zahra Hospital, Sofeh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Rezaeian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
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Specialist
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 5 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Al-Zahra Hospital, Dr. Ahmad Rezaeian -
dr.ahmadrezaeian@gmail.com

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

After the investigation of the researcher request and presentation of required documents will be accessible.

Comments