Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Budesonide and Rasa Sinex nasal sprays on control of allergic rhinitis patients

Protocol summary

Study aim
Comparison of the effect of budesonide and Rasasinex on the control of allergic rhinitis symptoms

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 100 patients.

Settings and conduct
1-place of the study: The lung and allergy clinic of Baqiyatallah Hospital in Tehran. 2-blinding: Medicines are prepared in the same packaging and appearance and size. Then they are coded based on codes already prepared using random numbers table The list of codes for each drug will remain with one of the executors until the end of the study. On drugs, numerical codes from 1 to 100 are recorded and patients receive drug no. 1 to 100 after entering the study, respectively. When analyzing the data, the code enforcers will provide the data analyzer in the form of A or B, so the study will be done in double-blind form.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all adults more than 18 years old; mild to moderate allergic rhinitis. Non-inclusion: allergy to black seed products and olive oil; active nasal bleeding; acute bronchitis; upper respiratory tract infection; pneumonia.

Intervention groups
Intervention group 1: budesonide spray recipient.
Intervention group 2: Rasasinex spray recipient.

Main outcome variables
Symptoms of congestion and nasal congestion and the extent to which these symptoms resolve; Sleep disorder; Disorders in daily activities, leisure or exercise; Disruption in work and school affairs; Painful symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110614006804N2**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-15, 1399/10/26**
Update count: **0**

Registration date
2021-01-15, 1399/10/26

Registrant information

Name
Mohammad Javad Behzadnia

Name of organization / entity
Baghyatallah medical sciences university

Country
Iran (Islamic Republic of)

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behzadnia@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-17, 1399/09/27

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Budesonide and Rasa Sinex nasal sprays on control of allergic rhinitis patients

Public title

Budesonide and Rasa Sinex effects on allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with allergic rhinitis who are confirmed by the clinical immunologist or Otolaryngologist

Exclusion criteria:

History of Asthma Acute bacterial sinusitis Recent topical or systemic Corticosteroid treatment Severe polyposis in rhino-endoscopy allergy to the black seeds and olive oil active nasal bleeding acute bronchitis pneumonia upper respiratory tract infection

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the medicines are prepared in the same packaging and appearance and size. Then they are coded based on codes already prepared using random numbers table. Randomization method: Permuted block randomization is done so that first all blocks of size 4 containing two codes A and B are prepared and then random blocks are selected by placement using random numbers table (25 blocks). These blocks form a sequence of 100 codes A and B, each of which is randomly assigned to one of the groups. The list of codes for each drug will remain with one of the executors until the end of the study. Numerical codes from 1 to 100 are recorded on drugs, and patients receive drug no. 1 to 100 after entering the study, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, first of all, we explain the patients about the random allocation in one of the two routine treatment. Then, according to the simple randomized method, they will put in group A or B. According to this, one of the drugs that are completely similar and only tagged as A, B will be prescribed for him/her.

Placebo

Not used

Assignment

Parallel

Other design features

none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah hospital

Street address

Trauma Research Center; Baqiyatallah University of Medical Sciences; Nosrati alley; Sheikh Bahaie street; Molla Sadra street; Vanaq square

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-12-17, 1399/09/27

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.043

Health conditions studied

1

Description of health condition studied

Allergy

ICD-10 code

J30.1

ICD-10 code description

Allergic rhinitis due to pollen

2

Description of health condition studied

Allergy

ICD-10 code

J30.2

ICD-10 code description

Other seasonal allergic rhinitis

Primary outcomes

1

Description

Allergic symptoms severity score based on the European Standard Allergy Questionnaire (ECRHS SCREENING QUESTIONNAIRE)

Timepoint

day 0 and day30.

Method of measurement

we will use the Demographic information and symptom severity questionnaire based on the European Standard Allergy Questionnaire (ECRHS SCREENING QUESTIONNAIRE), a validated sample of which is used in Persian.

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group is consisted of people who receive Rasa sinex spray. This spray is made by Artiman Company, contain olive oil and black seeds extract. The patient should use the drug twice a day every 12 hours in the nose for one month.

Category
Treatment - Drugs

2

Description
The second intervention group is consisted of those who receive Budesonide spray. This spray is manufactured by Cipla India company, named Naxonella, contain 0.5 mg/2 cc of inhaled glucocorticoids. The patient should use the drug twice a day every 12 hours in the nose for one month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah hospital

Full name of responsible person
Mohammad Javad Behzadnia

Street address
Baqiyatallah hospital, Nosrati alley, Sheikh Bahaie street, Molla Sadra street, Vanaq square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Gholamhosein Alishiri

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Trauma Research Center; Baqiyatallah University of Medical Sciences; Nosrati alley; Sheikh Bahaie street; Molla Sadra street; Vanaq square

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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Mohammad Javad Behzadnia

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Person responsible for scientific inquiries

Contact

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Position
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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
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After deleting the patient's identification data; data sharing could be possible.

When the data will become available and for how long
Immediately after the result publication.

To whom data/document is available
Only for academic and research requesting

Under which criteria data/document could be used
After researcher's request assessment, it could be possible for sharing the data.

From where data/document is obtainable
Via the corresponding author of the research.

What processes are involved for a request to access data/document
First of all a requesting email should send for the corresponding author;after the confirmation of the sender identity and his/her goal, we could share the data.

Comments