

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 21 8126 2012

Email address

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

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8126 2012

Email

behzadnia@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri

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

Phone

+98 21 8126 2012

Email

behzadnia@bmsu.ac.ir

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

Street address

Emergency department, Baghyatallah Hospital, Nosrati alley, Sheikh Bahaie street, Molla Sadra street, Vanaq square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8126 2012

Fax

+98 21 2255 8868

Email

behzadnia@bmsu.ac.ir

Person responsible for scientific 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

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

Phone

+98 21 8126 2012

Email

behzadnia@bmsu.ac.ir

Person responsible for updating data

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

Street address

Emergency department, Baghyatallah Hospital, Nosrati alley, Sheikh Bahaie street, Molla Sadra street, Vanaq square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8126 2012

Fax**Email**

behzadnia@bmsu.ac.ir

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