

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of effectiveness of the spray effect of Nigella Sativa plant on allergic rhinitis in children 3 to 15 years old

Protocol summary

Study aim

Effect of Nigella Sativa plant on allergic rhinitis in children 3 to 15 years old

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 50 patients. Random number table will be used for randomization.

Settings and conduct

The study site was the children's ward of Amirkola Hospital in Babol. The study population consisted of 50 samples. No blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 3 to 15 years old; with allergic rhinitis; no consumption of steroids, antihistamines and decongestants during 2 weeks before the study. Non inclusion criteria: Patients with chronic lung diseases other than allergic rhinitis, heart disease, kidney disease, metabolic disorders, malnutrition patients, previous allergy to black seed.

Intervention groups

Intervention group: This group receives standard treatment (including corticosteroid nasal spray, montazone, antihistamine, anti-leukotriene) and Rasa Synx nasal spray (black seed extract, made in Iran). Control group: This group receives only standard treatment.

Main outcome variables

IgE of serum and nasal secretion, Eosinophil count of serum and nasal secretion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054489N1**

Registration date: **2022-05-29, 1401/03/08**

Registration timing: **prospective**

Last update: **2022-05-29, 1401/03/08**

Update count: **0**

Registration date

2022-05-29, 1401/03/08

Registrant information

Name

Payam Payandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 314 8922

Email address

p.payandeh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-06, 1401/03/16

Expected recruitment end date

2022-09-07, 1401/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of the spray effect of Nigella Sativa plant on allergic rhinitis in children 3 to 15 years old

Public title

The efficacy of Black seed spray in the treatment of Nasal allergic inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children 3-15 years with allergic rhinitis No consumption of steroids, antihistamines and decongestants during 2 weeks before the study

Exclusion criteria:
Patients with chronic lung diseases other than allergic rhinitis Heart disease Kidney disease Metabolic disorders Malnutrition patients Previous allergy to black seed

Age
From **3 years** old to **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
After blocking, the samples are randomly divided into two groups of 25 using the table of random numbers in the intervention and control groups. The randomization unit is individual. The size of the blocks is 4 and in each block, each intervention group will be repeated twice. Sequences of size 4 will then be generated using Sealedenvelop.com – software. Using this randomly generated list, participants are assigned to one of two study groups. To hide the random allocation list, a special code will be assigned to each of the intervention groups that even the main executor of the project (supervisor) is not aware of. These codes are written on a piece of paper and placed in a sealed envelope. A unique code that is specific to each patient will be written on this paper as well as its envelope. All envelopes are placed in a larger box in random order and will be sealed in the box. The main researcher, after reviewing the inclusion criteria and obtaining informed consent, as well as registering the patient's details in a special form, with the cooperation of the random allocation list (this person is an expert other than the main researcher involved in the disease recruitment process And the sample is entered) is called and the patient is randomized.

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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4731741151

Approval date

2022-03-07, 1400/12/16

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.245

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30.4

ICD-10 code description

Allergic rhinitis, unspecified

Primary outcomes

1

Description

IgE of serum and nasal secretion

Timepoint

At first and one month later

Method of measurement

Laboratory test

2

Description

Eosinophil count of serum and nasal secretion

Timepoint

At first and one month later

Method of measurement

Laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes a puff of corticosteroid montazone nasal spray every 12 hours with an antihistamine (neotadine tablet or syrup) adjusted by weight, and an anti-leukotriene (5 to 10 mg daily by Montelocast depending on age) and Rasa Synx nasal

spray (black seed extract, made in Iran) one puff every twelve hours on each side of the nose (for three weeks).

Category

Treatment - Drugs

2

Description

Control group: Includes corticosteroid montazone nasal spray, one puff every 12 hours, antihistamine (neotadine tablet or syrup) adjusted by weight, and anti-leukotriene (Montelukast 5 or 10 mg daily, 1 depending on age).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kola Babol Children's Hospital

Full name of responsible person

Dr. Payam Payandeh

Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabian

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Taghizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Payam Payandeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Babol University of Medical Sciences; Ganjafrooz

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information is confidential on the basis of a contract
between the executor and the patients.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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