Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Nasal Probiotic Efficacy in Perennial Allergic Rhinitis Symptom Control and Recurrence

Protocol summary

Study aim
Determining the effects of probiotic nasal spray on clinical manifestations and recurrence of symptoms in patients with chronic allergic rhinitis

Design
Triple-blinded blocking method randomized clinical trial

Settings and conduct
In this study, allergic rhinitis patients were divided into two groups: control and intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with chronic allergic rhinitis who have clinical symptoms consistent with allergic rhinitis and a positive skin test with aeroallergens; age above 8 years and less than 50 years old; patient satisfaction. Exclusion criteria: Taking antibiotics while taking probiotics; consumption of compounds containing probiotics other than the medicine prescribed in the study; suspected drug allergy symptoms; the patient's non-cooperation in regular drug use and tests; pregnancy; taking immunosuppressive drugs; malnutrition; having a history of autoimmune disease or cystic fibrosis or active sinus infection; sinus pain; increased thick nasal secretions.

Intervention groups
In this clinical trial, patients with allergic rhinitis will divided into two groups: Control group – Participants will take intranasal Mometasone twice daily for three months. In the first month, also use a placebo nasal spray twice a day. Intervention group (Probiotic group) - In the first month, participants will use Mometasone nasal spray with probiotic nasal spray twice daily. In the second and third months, they will take only probiotic nasal spray twice daily.

Main outcome variables
Clinical symptoms; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150716023235N19**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date
2023-12-09, 1402/09/18

Registrant information

Name
Farahzad Jabbari Azad

Name of organization / entity
Allergy Research Center, Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Nasal Probiotic Efficacy in Perennial Allergic Rhinitis

Symptom Control and Recurrence

Public title
Nasal Probiotic Efficacy in Allergic Rhinitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with chronic allergic rhinitis who have clinical symptoms consistent with allergic rhinitis and a positive skin test with aeroallergens Age above 8 years and less than 50 years Patient satisfaction
Exclusion criteria:
Taking antibiotics while taking probiotics Consumption of compounds containing probiotics other than the medicine prescribed in the study Suspected drug allergy symptoms The patient's non-cooperation in regular drug use and tests Pregnancy Taking immunosuppressive drugs Malnutrition Having a history of autoimmune disease or cystic fibrosis Active sinus infection, sinus pain, increased thick nasal secretions
Age
From **8 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the blocking method will be used. In this way, study group A and control group B will be considered. According to the sample size of two groups, 8 random blocks of 4 are used. 1. AABB BBAA 2. BBAA AABB 3. ABAB AABB 4. BABA ABAB The random numbers table (https://www.Randomization.com) will be used to place the samples in the blocks randomly.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The sprays prepared in the intervention and control groups are completely similar in terms of shape, appearance, and smell. Allocation of people in two groups will be done randomly. The groups will be entered into SPSS software as A and B, and the analyst will not know about the intervention and control groups. In two follow-ups, one and three months, it will be done by a doctor who does not know about the division of patients into intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Approval date
2023-08-14, 1402/05/23
Ethics committee reference number
IR.MUMS.IRH.REC.1402.115

Health conditions studied

1

Description of health condition studied
Allergic Rhinitis
ICD-10 code
J30.1
ICD-10 code description
Allergic rhinitis due to pollen

Primary outcomes

1

Description
Nasal smear eosinophils
Timepoint
Before intervention, after 1 and 3 months of intervention
Method of measurement
Microscopical observation

2

Description
Clinical symptoms
Timepoint
Before intervention, after 1 and 3 months of intervention
Method of measurement
SNOT22 Questionnaire

3

Description
Quality of Life
Timepoint

Before intervention, after 1 and 3 months of intervention

Method of measurement

miniRQLQ Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: (Probiotic group) - In the first month, participants will use Mometasone nasal spray with probiotic nasal spray twice daily. In the second and third months, they will take only probiotic nasal spray twice daily.

Category

Treatment - Drugs

2

Description

Control group: control group – Participants will take intranasal Mometasone twice daily for three months. In the first month, also use a placebo nasal spray twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy clinic of Ghaem Hospital

Full name of responsible person

Rana Tafrishi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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Grant name

Mashhad University of Medical Sciences Faculty Grant

Grant code / Reference number

4012452

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Rana Tafrishi

Position

fellowship of allergy and clinical immunology

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for scientific

inquiries

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Position
Proffessor

Latest degree
Subspecialist

Other areas of specialty/work
Allergy and clinical imuunology

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Position
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Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Not applicable

When the data will become available and for how long
Not applicable

To whom data/document is available
Not applicable

Under which criteria data/document could be used
Not applicable

From where data/document is obtainable
Not applicable

What processes are involved for a request to access data/document
Not applicable

Comments