

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 be 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)

Phone

+98 51 1801 2770

Email address

jabbarif@mums.ac.ir

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

Street address

Ahmad abad AVE, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

991991766

Phone

+98 935 609 1846

Email

ranatafrishi96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farahzad Jabbari Azad

Street address

Ahmad abad AVE, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

991991766

Phone

+98 915 316 7868

Email

jabbarif@mums.ac.ir

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

Street address

Ahmad abad AVE, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

991991766

Phone

+98 51 3801 2298

Email

ranatafrishi96@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farahzad Jabbari Azad

Position

Proffessor

Latest degree

Subspecialist

Other areas of specialty/work

Allergy and clinical imuunology

Street address

Department of Immunology and Allergy, Hospital
Ghaem, Ahmadabad streets, Mashhad Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9119-91766

Phone

+98 51 3801 2298

Email

jabbarif@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Rana Tafrishi

Position

student

Latest degree

Specialist

Other areas of specialty/work

Allergy and clinical imuunology

Street address

epartment of Immunology and Allergy, Hospital
Ghaem, Ahmadabad streets, Mashhad Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

991991766

Phone

+98 51 3801 2298

Email

ranatafrishi96@gmail.com

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