

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The evaluation of Probiotic lactocare effect on immune responses and clinical manifestation in patients with perennial allergic rhinitis

#### Protocol summary

##### Study aim

Probiotic prescribing on immune responses and clinical manifestations in patients with perennial allergic rhinitis

##### Design

Pragmatic, community based, parallel group, double blind, randomised controlled trial

##### Settings and conduct

Before and 6 months after the intervention, Brachial vein of 5cc patients is taken to perform flow cytometric studies and serum preparation for the sample bank. Also, the miniRQLQ and SNOT22 questionnaires, which are related to quality of life and severity of the disease, are completed before and after the intervention by the patients.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: All patients with perennial allergic rhinitis aged 5 to 5 years old living in Mashhad and surrounding cities who have positive skin tests with aeroallergen and who are required to collaborate.  
exclusion criteria: Patients with a history of autoimmune disease, patients who have systemic corticosteroids or immunosuppressive drugs that are effective on the immune system, pregnant women, immunocompromised patients, patients with allergic asthma, Malnutrition patients, and patients Antibiotics are used for any reason during the use of the probiotic.

##### Intervention groups

Patients are divided into two equal groups (in each group of 15) using a randomized block method. In addition to common allergic rhinitis treatments, lactocare is prescribed and in the other group, in addition to the usual treatments, placebo is prescribed.

##### Main outcome variables

The level of IL25 proteins affects the frequency of Th1, Th2, Th17, and Treg cells, as well as the expression of T-bet, GATA3, RORgamma t and FOXP3 transcription factor gene expression at the start of the process, six months after the course.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150716023235N14**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **prospective**

Last update: **2019-01-14, 1397/10/24**

Update count: **0**

##### Registration date

2019-01-14, 1397/10/24

##### 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

2019-02-09, 1397/11/20

##### Expected recruitment end date

2020-09-20, 1399/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The evaluation of Probiotic lactocare effect on immune responses and clinical manifestation in patients with perennial allergic rhinitis

**Public title**

The evaluation of Probiotic lactocare effect on patients with perennial allergic rhinitis

**Purpose**

Basic science

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with perennial allergic rhinitis aged 5 to 5 years old. Who have positive skin tests with aeroallergen. They have to collaborate.

**Exclusion criteria:**

Patients with a history of autoimmune disease. patients who have systemic corticosteroids or immunosuppressive drugs that are effective on the immune system. pregnant women, immunocompromised patients, patients with allergic asthma. malnourished patients who have either The reason why you take antibiotics when taking Probiotic.

**Age**

From **5 years** old to **50 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of block randomization Unit of randomization individual Tools used in randomization computer softwares

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants will receive the same drug or placebo The main researcher is unaware of the effect of the drug on improving quality of life and effective immune responses.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Allergy Research Center, Ghaem Hospital, Mashhad, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2018-12-19, 1397/09/28

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1397.477

**Health conditions studied****1****Description of health condition studied**

Allergic rhinitis

**ICD-10 code**

J30.3

**ICD-10 code description**

Other allergic rhinitis

**Primary outcomes****1****Description**

Interleukin 25 ,Quality of life

**Timepoint**

Before intervention, 6 months after intervention

**Method of measurement**

quality of life:miniRQLQ and SNOT22 questionnaires, interleukin 25:elisa kit

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:In addition to the usual treatments for allergic rhinitis, Steroids nasal spray Rhinocort, a lactocare probiotic daily that contains strains: lactobacillus casei, lactobacillus acidophilus, lactobacillus rhamnosus, lactobacillus bolgaricus, bifidobacterium bereve, bifidobacterium longum, streptococcus thermophilus is prescribed.The duration of the intervention is 6 months. probiotic lactocare from the Zist Takhmir company is Iran.

**Category**

Treatment - Drugs

## 2

### Description

Control group:In addition to the usual treatments, Steroids nasal spray Rhinocort,a placebo is prescribed daily.The duration of the intervention is 6 months . The placebo from the Zist Takhmir company is Iran.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Doctor Farahzad Jabari Azad

##### Street address

Iran, Mashhad, Ahmadabad, Ghaem Hospital, Allergy Research Center

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91778-99191

##### Phone

+98 51 3841 2081

##### Email

Arezoofaridzadeh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Doctor Mohsen Tafaghodi

##### Street address

Ahmad Abad Boulevard, Ghaem Hospital

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##### Province

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##### Email

JabbariF@mums.ac.ir

#### Grant name

Allergy Research Center, Bu Ali Research Center

#### Grant code / Reference number

#### 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

Arezoo Faridzadeh

##### Position

Medical doctor.PhD candidate

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Immunology

##### Street address

Allergy Research Center, Ghayegh Hospital, Ahmedabad Boulevard, Mashhad

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Arezoo Faridzadeh

##### Position

Medical doctor.PhD candidate

##### Latest degree

Medical doctor

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Arezo Faridzadeh

**Position**

Medical doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Immunology

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Ahmedabad Blvd, Mashhad

**City**

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**Province**

Razavi Khorasan

**Postal code**

9177899191

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

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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**

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