

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

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Mohsen Tafaghodi

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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

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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

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Position

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Latest degree

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Other areas of specialty/work

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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