

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial to evaluate the impact of synbiotic on the clinical and immunological efficiency of allergen immunotherapy in patients with allergic rhinitis and compared with placebo

Protocol summary

Summary

Initially, we select 30 patients referred to the department of immunology - allergy Ghaem hospital with perennial allergic rhinitis which upon clinical criteria and prick tests their sensitivity to aeroallergens was approved. After explaining the advantages and disadvantages of immunotherapy and probiotics and consent documents to enter the trial, they were studied. Patients were randomly assigned to three groups receiving symbiotic plus immunotherapy, placebo plus immunotherapy and symbiotic without immunotherapy. Used symbiotic was made by Zist takhmir supplement company and consist of Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus. In addition Fructooligosaccharide in this product is used as a probiotic. The study was done double blind. Before starting treatment based on clinical examination and standardized questionnaire, clinical manifestation and anti allergy drug recorded and 7 cc heparinized blood from each patient is prepared. Then CD3, CD4, CD25 and FOXP3 are determined by flow cytometry. In addition intracellular expression of IL-4 and IFN-gamma by flow cytometry and specific IgE by ELISA is determined. Also periodic clinical assessment by fellow of allergy and clinical immunology is done. Cluster immunotherapy in accordance with the attached protocol is performed and 2 month symbiotic or placebo is administered. After 2th and 6th month evaluation is repeated . Finally, the results of the three groups were compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120123235N4**

Registration date: **2016-08-29, 1395/06/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-29, 1395/06/08

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

Mashhad University of Medical Sciences

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2016-07-31, 1395/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the impact of synbiotic on the clinical and immunological efficiency of allergen immunotherapy in patients with allergic rhinitis and compared with placebo

Public title

Effect of symbiotic on Immunotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with persistent allergic rhinitis; Mashhad residents and surrounding towns; Have a positive skin test with Aeroallergen; Cooperate in projects Exclusion criteria: A history of autoimmune disease; Systemic corticosteroids or immunosuppressive drugs consumption and effective on immune system; Pregnant Women; Patients with immunodeficiency; Patients with malnutrition; Use Antibiotic during synbiotic consumption

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mashhad University of Medical Sciences

Street address

Daneshgah Street Qureshi building

City

Mashhad

Postal code**Approval date**

2015-07-29, 1394/05/07

Ethics committee reference number

IR.MUMS.fm.REC.1394.154

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

Perennial allergic rhinitis

ICD-10 code

J30.3

ICD-10 code description

Other allergic rhinitis

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

Quality of life

Timepoint

Before the intervention and two month later

Method of measurement

Snot 22 questionnaire

2**Description**

IL4

Timepoint

Before the intervention and two month later

Method of measurement

Flow cytometry

3**Description**

T-reg

Timepoint

Before the intervention and two month later

Method of measurement

Flow cytometry

4**Description**

IFN- gamma

Timepoint

Before the intervention and two month later

Method of measurement

Flow cytometry

Secondary outcomes**1****Description**

Systemic reactions to immunotherapy

Timepoint

At every turn immunotherapy

Method of measurement

Clinical

Intervention groups

1

Description

In intervention group synbiotic capsule give once a day for two month

Category

Treatment - Drugs

2

Description

In control group placebo capsule give once a day for two month with immunotherapy

Category

Treatment - Drugs

3

Description

In Intervention group synbiotic capsule give once a day for two month with immunotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy Clinic Ghaem Hospital

Full name of responsible person

Nasrin Moazzen, MD

Street address

Allergy Clinic Ghaem Hospital, Ahmad Abad Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Mashhad University of Medical Sciences

Street address

Daneshgah Ave, Ghoreishi, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

940113

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nasrin Moazzen, MD

Position

Fellows in Training

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty