Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Fructooligusacaride 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 cytometery. In addition intracellular expression of IL-4 and IFN-gamma by flow cytometery 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
Allergy Research Center, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
Full name of responsible person
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Associate Professor
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Person responsible for updating data

Contact

Name of organization / entity
mashhad university of medical science

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nasrin moazzen, MD

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fellow of Allergy and Cilinical Immunology

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