

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effects of probiotic on clinical findings in patients with allergic rhinitis and asthma

#### Protocol summary

##### Study aim

The present study aims to investigate the role of probiotics as one of the treatments for preventing allergic rhinitis and asthma, along with routine therapies, in order to reduce the burden of diseases.

##### Design

In this double-blinded randomized clinical trial, 30 patients will be studied through 2 groups of 15 participants. The intervention group will be under the treatment of Familact probiotic (Zist Takhmir, Iran) together with the previous common medication. The control group will receive only previous routine medications.

##### Settings and conduct

The study is conducted at Tabriz Imam Reza Hospital. According to the checklist, the study variables of the patients before treatment and after treatment will be analyzed. Patients randomly entering into two groups, probiotic and placebo are delivered to people for eight weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All people over the age of 15, including the male and the female, who have allergic rhinitis. All people over the age of 15, including male and females, who have asthma. Non inclusion criteria: Using antibiotics in the past 4 weeks; Food allergy; Lactose intolerance; suffering from chronic diseases; Use of corticosteroids; Suffering from underlying diseases other than asthma; Suffering from other kinds of rhinitis and respiratory diseases

##### Intervention groups

Intervention group: Individuals with allergic rhinitis and asthma who receive a probiotic supplement for 8 weeks in addition to their previous routine treatment. Control group: People with allergic rhinitis and asthma who receive a placebo for 8 weeks in addition to previous routine therapy.

##### Main outcome variables

Cough, post nasal drip, nasal discharge, nasal polyps,

sleep disturbances, dyspnea, snoring, turbinates hypertrophy and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161215031429N3**

Registration date: **2018-10-02, 1397/07/10**

Registration timing: **prospective**

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

##### Registration date

2018-10-02, 1397/07/10

##### Registrant information

##### Name

Yalda Jabbarimoghadam

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 161 3913

##### Email address

jabbariy@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Approved funds of Tabriz University of Medical Sciences

##### Expected recruitment start date

2018-10-07, 1397/07/15

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of probiotic on clinical findings in patients with allergic rhinitis and asthma

**Public title**

The effect of probiotics on allergic rhinitis and asthma

**Purpose**

Treatment

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

All people over the age of 15, including the girl and the boy, who have allergic rhinitis. All people over the age of 15, including boys and girls, who have asthma.

**Exclusion criteria:**

Using antibiotics in the past 4 weeks Food allergy Lactose intolerance suffering from chronic diseases Use of corticosteroids Suffering from underlying diseases other than asthma Suffering from other kinds of rhinitis and respiratory diseases

**Age**

From **15 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After the primary visit, the participants who meet the inclusion criteria will be allocated by randomization software into two groups. The random allocation will be done through blocks of size 8 in order to make balance in number between male and female.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After signing informed consent by all participants, the participants will be numbered by a tertiary investigator and the numbers will be entered to the randomization software. After allocating the participants to the two groups by randomization software, the case and control groups will be determined. Then the supplements and placebo will be given to the secondary investigator, who is blind to the sequence of entering to the study. Finally, the supplements and placebo will be given to the patients of each group which is determined by the tertiary investigator who is not aware of the content of the capsules.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Golghast Ave.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166857513

**Approval date**

2017-08-31, 1396/06/09

**Ethics committee reference number**

IR.TBZMED.REC.1396.461

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

Asthma

**ICD-10 code**

J45.0

**ICD-10 code description**

Predominantly allergic asthma

**2****Description of health condition studied**

Allergic Rhinitis

**ICD-10 code**

J30

**ICD-10 code description**

Vasomotor and allergic rhinitis

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

Cough

**Timepoint**

Before intervention and 4 and 8 weeks after intervention

**Method of measurement**

Standard Questionnaire

## 2

### **Description**

Post Nasal Drip

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

Physical Examination

## 3

### **Description**

Nasal Discharge

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

Physical Examination

## 4

### **Description**

Nasal polyps

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

Physical Examination

## 5

### **Description**

Night snoring

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

Standard questionnaire

## 6

### **Description**

Sleep disturbances

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

Standard questionnaire

## 7

### **Description**

Turbinates hypertrophy

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

Physical Examination

## 8

### **Description**

Quality of life

### **Timepoint**

Before intervention and 4 and 8 weeks after intervention

### **Method of measurement**

SF-36 quality of life questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Familact probiotic capsules produced by Zist Takhmir Co. (Tehran, Iran) will be administered to patients with asthma and allergic rhinitis for 8 weeks, along with routine therapeutic treatment.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo capsules produced by Zist Takhmir Co. (Tehran, Iran) will be administered to patients with asthma and allergic rhinitis for 8 weeks, along with routine therapeutic treatment.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Hassan Rezapour

##### **Street address**

Golghast Ave.

##### **City**

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##### **Postal code**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Hassan Rezapour

##### **Street address**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hassan Rezapour

**Position**

ENT Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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## Person responsible for scientific inquiries

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Yalda Jabari Moghaddam

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

Hassan rezapour

**Position**

ENT Assistant

**Latest degree**

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**Other areas of specialty/work**

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prezapour78@yahoo.com

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**  
Yes - There is a plan to make this available

**Analytic Code**  
Yes - There is a plan to make this available

**Data Dictionary**  
Yes - There is a plan to make this available

**Title and more details about the data/document**  
Only a portion of the data, such as its original information, can be shared.

**When the data will become available and for how long**  
Start the access period 6 months after printing the results

**To whom data/document is available**  
Data will only be available to researchers working in

academic and scientific institutions .

**Under which criteria data/document could be used**  
All academic and researcher / all statistical analyzes are unhelpful . Use of data with the permission of the researcher and the maintenance of relevant rights .

**From where data/document is obtainable**  
Visit the Vice-Chancellor of Research and Technology of Tabriz University of Medical Sciences or contact the researcher . Phone number: 989143821138+ or home phone: 00984133339589

**What processes are involved for a request to access data/document**  
Access to the data is possible after two weeks after submitting to the relevant units and requesting a maximum of two weeks

**Comments**