

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)

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+98 914 161 3913

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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.

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emamrezahosp@Gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hassan Rezapour

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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

Contact

Name of organization / entity

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Full name of responsible person

Yalda Jabari Moghaddam

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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