

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of therapeutic effect of probiotic supplement to improvement of signs and immunomodulation in patients with asthma

Protocol summary

Study aim

Determine the therapeutic effect of probiotic supplement to improvement of signs and immunomodulation in patients with asthma

Design

Double-blind parallel placebo-controlled randomised clinical trial

Settings and conduct

The study will be performed on patients with asthma in Semnan province that visited by physician in university clinic. The simple randomization using cards shuffling will be done. Allocation concealment will be considered via sealed and opaque envelopes. Briefly, 20 envelopes contain probiotic supplement and another 20 envelopes have placebo with their own specific codes that will be prescribed using cards shuffling method. After probiotic supplement prescription and placebo during 60 days, laboratory and clinical variables will be considered.

Participants/Inclusion and exclusion criteria

Inclusion criteria for participants includes all patients with asthma who have dry- or with slight sputum cough, wheezing, dyspnea sign and sometimes have the chest tightness or pain symptom and exclusion criteria includes patients who have lung infectious diseases such as pneumonia, coronary heart disease, lung cancer, primary and secondary immunodeficiency, and patients who smoke and take antibiotics. Inclusion and exclusion criteria is same for both intervention and control groups.

Intervention groups

The intervention group includes patients who receive probiotic supplement and control group includes patients that receive placebo.

Main outcome variables

Outcomes related to intervention on patients will include cellular, molecular and clinical changes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191220045830N1**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **prospective**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Sina Sadrifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 0532

Email address

sadrifarsina@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2022-03-17, 1400/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of probiotic supplement to improvement of signs and immunomodulation in patients with asthma

Public title

Evaluation of probiotic effect on asthma

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with asthma who have dry- or with slight sputum cough sign. All patients with asthma who have wheezing sign. All patients with asthma who have dyspnea sign. All patients with asthma who sometimes have the chest tightness or pain symptom.

Exclusion criteria:

The patients who have lung infectious diseases such as pneumonia. The patients who have coronary heart disease. The patients who have lung cancer. The patients who have primary immunodeficiency. The patients who have secondary immunodeficiency such as HIV. The patients who smoke. The patients who take antibiotics.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization using cards shuffling will be performed. Briefly, 40 cards will be numbered and each card is representative of each envelope contain probiotic supplement or placebo. Allocation concealment will be done via sealed and opaque envelopes. Briefly, 20 envelopes contain probiotic supplement and another 20 envelopes have placebo with their own specific codes that will be prescribed using cards shuffling method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding of patients will be obtained by use of same shape capsules the contain either probiotic supplement or placebo. Blinding of researcher and physician will be done using sealed and opaque envelopes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2019-12-17, 1398/09/26

Ethics committee reference number

IR.SEMUMS.REC.1398.226

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

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

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

Gene expression changes of T-bet, GATA3, Ror γ t and FoxP3 transcription factors in peripheral blood mononuclear cells

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using real-time PCR method

2**Description**

Frequency changes of Treg cells in peripheral blood

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using a flow cytometry

3**Description**

Gene expression changes of miR 21, miR 155, miR146a, miR 126, miR 16 and miR133b in serum

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using real-time PCR method

4

Description

Changes in serum level of IL-4 and IFN- γ

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using ELISA method

5

Description

Gene expression changes of IL-6, IL-17, IL-21 and TGF- β in peripheral blood mononuclear cells

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using real-time PCR method

6

Description

Change rates of Forced Expiratory Volume in first second (FEV1)

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using Spirometry

7

Description

Change rates of Forced Vital Capacity (FVC)

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using Spirometry

8

Description

Change rates of Forced Expiratory Volume in first second (FEV1)/Forced Vital Capacity (FVC)

Timepoint

Before and 60 days after beginning of intervention

Method of measurement

Using Spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive one probiotic supplement capsule include 1 billion colony forming unit (CFU) from Zisttakhmir company called Lactocare every day after the meal for 60 days.

Category

Treatment - Drugs

2

Description

Control group will receive one placebo capsule include starch from Zisttakhmir company every day after the meal for 60 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Farhad Malek

Street address

Kosar hospital, Amin Blvd., Golestan Town., Semnan

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farhadmalek42@yahoo.com

Web page address

<https://kosarhos.semums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Semnan University of Medical Sciences and Health Services Headquarters., Basij Blvd

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Web page address

<https://semums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Rasoul Baharlou

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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

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Full name of responsible person

Sina Sadrifar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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

Yes - There is a plan to make this available

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

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

Title and more details about the data/document

The clinical and laboratory data on patients with asthma that treated with drug and placebo can be shared

When the data will become available and for how long

6 month after result publication

To whom data/document is available

It will be accessible to university, scientific and production

sections

Under which criteria data/document could be used

Data can be analysed and usable by clinical institutes

From where data/document is obtainable

Department of Internal Medicine, Kosar hospital, Semnan University of Medical Sciences Department of Immunology, School of Medicine, Semnan University of Medical Sciences 1- Dr Rasoul Baharlou email: baharlour@gmail.com 2- Dr Farhad Malek email:

farhadmalek42@yahoo.com

What processes are involved for a request to access data/document

The applicant can ask researchers to consider their request after article publication via formal letter- university or scientific institute and production section using email to receive files

Comments