

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the therapeutic effect of adding probiotic oral powder to standard treatment for the improvement of mild to moderate asthma in children

Protocol summary

Study aim

Evaluating the effectiveness of adding probiotic to standard treatment in children with mild to moderate asthma for the improvement of asthma symptoms

Design

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized

Settings and conduct

The aim of this study was to investigate the effect of probiotic on child's asthma in specialty and postgraduate specialty clinic of Heshamateyeh Hospital in Sabzevar city. In this study, participants and those who evaluated the outcome in children were unaware of how children were grouped. Children are randomly assigned to the intervention group (probiotics capsule) and the control (placebo capsules). The response to treatment is evaluated using the PRAM questionnaire at the end of The 30th day after starting intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All of 3 to 8 years old children with mild to moderate asthma Exclusion criteria: Children Under 3 and over 8 years, Children with severe asthma, Children with seasonal allergies.

Intervention groups

Intervention group: The consumption of the probiotic 500mg capsule (made in Zist Takhmir Co.) after three meals for one month Control group: The consumption of placebo capsule (Made in Iran Drug Laboratories) after three meals for one month

Main outcome variables

Control of asthma symptoms, Disruptions to go to the school due to a severe cough, The frequency of asthma attacks, Use nasal spray or nebulizer, The frequency of waking up at night, Control of cough symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180115038378N1**

Registration date: **2018-09-12, 1397/06/21**

Registration timing: **retrospective**

Last update: **2018-09-12, 1397/06/21**

Update count: **0**

Registration date

2018-09-12, 1397/06/21

Registrant information

Name

elahe razmara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3764 2423

Email address

ekramimilad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-15, 1397/03/25

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of adding probiotic oral powder to standard treatment for the improvement of mild to moderate asthma in children

Public title

Effect of probiotic supplements on children's asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All 3 to 8 years old children with mild to moderate asthma

Exclusion criteria:

Age under 3 and over 8 People with seasonal allergies Children with severe and persistent asthma

Age

From **3 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization based on permutation. Accordingly, 30 blocks were allocated to patients, in each block 2 from A treatment group and 2 from the B treatment group were placed. Eventually, after completion of the blocks, group A was treated with probiotic capsule and Group B treated with placebo capsule.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person in the study will be assigned code A and B, that the researcher will only be known of the type of groups. The outcome evaluator and practitioner is unaware of the groups. It should be noted that Probiotic and placebo are similar in appearance, color and packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.MEDSAB.REC.1396.179

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Control of asthma symptoms

Timepoint

The 30th day after starting intervention

Method of measurement

PRAM standard questionnaire

Secondary outcomes

1

Description

Disruption to go to the school due to a severe cough.

Timepoint

The 30th day after starting intervention

Method of measurement

PRAM standard questionnaire

2

Description

The frequency of asthma attacks

Timepoint

The 30th day after starting intervention

Method of measurement

PRAM standard questionnaire

3

Description

Use Nasal spray or Nebulizer

Timepoint

The 30th day after starting intervention

Method of measurement

PRAM standard questionnaire

4**Description**

The frequency of waking up at night

Timepoint

The 30th day after starting intervention

Method of measurement

PRAM standard questionnaire

5**Description**

Control of cough symptoms

Timepoint

The 30th day after starting intervention

Method of measurement

PRAM standard questionnaire

Intervention groups**1****Description**

Intervention group: Patients in this group consume 500 mg of Fmilact probiotics (produced by Zist Takhmir Company) for one month after three meals.

Category

Treatment - Drugs

2**Description**

Control group: Patients in this group consume placebo capsules (prepared in the Iranian Pharmacy Lab) for one month after three meals.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Heshmatiyeh hospital

Full name of responsible person

Elahe Razmara Farzaghi

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Heshmatiyeh Hospital, Asadabady Ave., Sabzevar Town

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

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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

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Dr Homan Tehrani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available