

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Effect of a new synbiotic mixture on atopic dermatitis in children

#### Protocol summary

medical sciences

##### Summary

In a randomized, double-blind, placebo-controlled study, 40 infants and children aged 3 months to 6 years with mild to severe AD will receive either a mixture of 7 probiotic strains or placebo for 8 weeks. The Severity Scoring of Atopic Dermatitis (SCORAD) will be recorded at baseline and also at 4 and 8 weeks of treatment. IL-4 and IFN-gamma concentrations will be assessed on the supernatant after polyclonal stimulation of mononuclear cells culture

##### Expected recruitment start date

2007-02-02, 1385/11/13

##### Expected recruitment end date

2009-02-02, 1387/11/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201010204976N1**

Registration date: **2011-02-09, 1389/11/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-09, 1389/11/20

##### Registrant information

###### Name

Hamid Ahanchian

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3801 2469

###### Email address

ahanchianh@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

vice chancellor for research, Mashhad University of

##### Scientific title

Effect of a new synbiotic mixture on atopic dermatitis in children

##### Public title

Synbiotic in Atopic Dermatitis in children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion: Aged from 3 months to 6 years Mild to severe Atopic dermatitis Exclusion: Prior exposure to probiotics Were currently taking a course of antibiotics, or had other major medical problems

##### Age

To **6 years** old

##### Gender

Both

##### Phase

0

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **40**

##### 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 medical sciences etic committee

##### Street address

Ghoreishi bulding, Daneshgah street, Mashhad, Iran

##### City

Mashhad

##### Postal code

#### Approval date

2008-05-21, 1387/03/01

#### Ethics committee reference number

1062008

## Health conditions studied

### 1

#### Description of health condition studied

Atopic Dermatitis

#### ICD-10 code

L-20.8

#### ICD-10 code description

infantile (acute)(chronic)

## Primary outcomes

### 1

#### Description

Severity of Atopic Dermatitis

#### Timepoint

At the beginning of the study, 2 months after intervention

#### Method of measurement

SCORAD method

## Secondary outcomes

### 1

#### Description

Cytokine profile(IL-4, INF- Gamma )

#### Timepoint

At the beginning of the study, 2 months after intervention

#### Method of measurement

ELISA on supernatant of Blood lymphocyte culture

## Intervention groups

### 1

#### Description

Participants were randomly divided into two groups.  
Intervention: Patients in the probiotic group received synbiotic containing 1 billion Colony Forming Unit(CFU) of Protexin Restore: a mixture of Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium infantis, Lactobacillus bulgaricus and Fructooligosaccharide (Protexin healthcare, Somerset, United Kingdom), in the form of freeze dried powder twice daily for 8 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

CONTROL: The control group received placebo powder without probiotics which were matched for size, shape, and volume of contents and manufactured by the same company, twice daily for 8 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem hospital

##### Full name of responsible person

Dr Hamid Ahanchian

##### Street address

Pediatric Allergy department, Ghaem hospital, Ahmad Abad Blvd, Mashhad, Iran

##### 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

Dr Ramezani

##### Street address

Ghoreishi bulduing, Daneshgah Street, Mashhad, Iran

##### City

Mashhad

#### Grant name

#### Grant code / Reference number

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

Mashhad University Medical Sciences

**Full name of responsible person**

Hamid Ahanchian

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Ghaem hospital, Ahmad Abad blvd, Mashhad iran

**City**

mashhad

**Postal code****Phone**

+98 51 1801 2522

**Fax****Email**

ahanchianh@mums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Hamid Ahanchian

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email**

Ahanchianh@mums.ac.ir

**Web page address****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*