

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

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+98 51 1801 2522

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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