

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of synbiotics in reduction scoring of childhood atopic dermatitis (SCORAD)

Protocol summary

Summary

In this randomized double blind-placebo controlled trial we aimed to evaluate the effect of synbiotic supplementation in treatment of childhood atopic dermatitis (AD). We recruited children aged 1–36 months with moderate to severe Atopic Dermatitis (SCORAD>25). Exclusion criteria were age less than 1 month and more than 36 months, SCORAD<25, and primary chronic disease. Infants were randomized (n=40) and received either Synbiotic (Probiotic plus Prebiotic) (n=20) or placebo (n=20) daily as a powder for two months. Emollient (Eucerin) and topical corticosteroid (Hydrocortisone) were permitted to use daily as a routine treatment of atopic dermatitis in both intervention and control groups. Children were scored for severity of atopic dermatitis (SCORAD) at the beginning and end of study as primary outcome measure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009094719N2**

Registration date: **2010-12-20, 1389/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-20, 1389/09/29

Registrant information

Name

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Name of organization / entity

Iranian Asthma Allergy and Immunology Research Institute

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iranian Asthma Allergy and Immunology Research Institute

Expected recruitment start date

2007-01-01, 1385/10/11

Expected recruitment end date

2008-01-01, 1386/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of synbiotics in reduction scoring of childhood atopic dermatitis (SCORAD)

Public title

Effect of synbiotics in treatment of childhood atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were children aged 1–36 months with moderate to severe Atopic Dermatitis (SCORAD>25). Exclusion criteria were age less than 1 month and more than 36 months, SCORAD<25, recurrent infections (as an evidence of immunodeficiency), congenital abnormality, chronic disease and problem in eating and administration of systemic corticosteroids.

Age

To **3 years** old

Gender

Both

Phase

N/A

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

Iranian Asthma Allergy and Immunology Ethics Committee

Street address

Children Medical Center Hospital ,Gharib Street

City

Tehran

Postal code

Approval date

2008-11-04, 1387/08/14

Ethics committee reference number

238/412/پ

Health conditions studied

1

Description of health condition studied

atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Dermatitis and eczema

Primary outcomes

1

Description

severity of atopic dermatitis according to SCORAD

Timepoint

before and two months after intervention

Method of measurement

SCORAD table

Secondary outcomes

1

Description

adverse reaction

Timepoint

every 2 weeks

Method of measurement

asking from parents

Intervention groups

1

Description

In the intervention group, children daily took one sachet containing 10 milligram mixture of 1×10^9 CFU/ of seven strain probiotics plus prebiotic (990 milligram fructo-oligosaccharides). We instructed usual treatment of atopic dermatitis including bathing with lukewarm water, moisturizing cream (Eucerin) and topical corticosteroid (Hydrocortisone 1%) once time, daily for two month in intervention group

Category

Treatment - Drugs

2

Description

In the control group, children daily took one sachet for oral use ,containing 1000 milligram sucrose. similarly We instructed usual treatment of atopic dermatitis including bathing with lukewarm water, moisturizing cream (Eucerin) and topical corticosteroid (Hydrocortisone 1%) once time, daily for two month in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

children medical center hospital,allergy ward

Full name of responsible person

alireza shafiei

Street address

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian Asthma Allergy and Immunology Research

Institu
Full name of responsible person
Mostafa Moin
Street address
Chidren Medical Center Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian Asthma Allergy and Immunology Research Institu
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

Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Masood Movahedi
Position
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Other areas of specialty/work
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Person responsible for updating data

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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