

# 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

Alireza Shafiei

###### Name of organization / entity

Iranian Asthma Allergy and Immunology Research Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7772 2452

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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  $1 \times 10^9$  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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*