

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Effectiveness of prebiotic in atopic dermatitis reduction in 7-24 months old children living in Isfahan

#### Protocol summary

##### Summary

The main objective of this study was to determine whether consumption of prebiotics can reduce the severity of AD in 7-24 month old children in Isfahan. In a double blind controlled trial study seventy 7-24 months old full term children with Atopic Dermatitis (AD), delivered by cesarean section, with no other chronic diseases, not treated with corticosteroid or any other immunosuppressive drugs, were randomly assigned into 2 groups. The intervention group received prebiotic (fructooligosaccharide + inulin) and the control group received placebo (dextrin powder) for 3 months. At the baseline and the end of the intervention SCORAD test questionnaire was completed for all children by a physician.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138809072779N1**

Registration date: **2010-02-16, 1388/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-02-16, 1388/11/27

##### Registrant information

##### Name

Fereydoun Siassi

##### Name of organization / entity

School of Public Health, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 4924

##### Email address

siassif@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences and Health Services

##### Expected recruitment start date

2008-03-21, 1387/01/02

##### Expected recruitment end date

2009-03-19, 1387/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of prebiotic in atopic dermatitis reduction in 7-24 months old children living in Isfahan

##### Public title

Effectiveness of prebiotic in atopic dermatitis reduction in 7-24 months old children living in Isfahan

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 7-24 months old children with atopic dermatitis (AD); full term with normal weight at birth; delivered by cesarean, weaning food started after 6 months; willingness of the parents for participation in the trial. Exclusion criteria: Treatment with corticosteroid or any immunosuppressive drugs during the last 3 months prior to the trial; having any chronic diseases except AD.

##### Age

From **1 year** old to **2 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 70

## 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

Vice Chancellor for Research, Ethical Clearance Approval, Tehran University of Medical Sciences and

##### Street address

Ghods St., Keshavarz Blvd.

##### City

Tehran

##### Postal code

1417653761

#### Approval date

empty

#### Ethics committee reference number

130/1429

## Health conditions studied

### 1

#### Description of health condition studied

Atopic dermatitis

#### ICD-10 code

L20.8

#### ICD-10 code description

Other Atopic dermatitis

## Primary outcomes

### 1

#### Description

Severity of atopic dermatitis

#### Timepoint

Monthly

#### Method of measurement

SCORAD (SCORing Atopic Dermatitis)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control: 0.8g maltodextrin (placebo) per 100 ml consuming milk for 3 months.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention: 0.8g fructo-oligosaccharides + inulin mixture (prebiotic) per 100 ml consuming milk for 3 months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Specialized Children Clinic of Al\_Zahra Hospital in Isfahan

##### Full name of responsible person

Dr. Fariborz Zandieh

##### Street address

Department of Pediatrics of AlZahra Hospital, School of Medicine, Isfahan University of Medical Sciences

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Under Secretary of Research, Tehran University of Medical Sciences and Health Services (TUMS)

##### Full name of responsible person

D. Akbar Fotouhi, Undersecretary of Research, TUMS

##### Street address

Keshavarz Blvd, Corner of Ghods Ave, TUMS Administrative bldg, 6th floor

##### City

Tehran

#### Grant name

پایان نامه کارشناسی ارشد

#### Grant code / Reference number

132/806

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Under Secretary of Research, Tehran University of  
Medical Sciences and Health Services (TUMS)

**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**

School of Public Health; Tehran University of Medical  
Sciences and Health Services

**Full name of responsible person**

Nila Ghanei

**Position**

MS student

**Other areas of specialty/work**

**Street address**

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**Person responsible for scientific  
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**Full name of responsible person**

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**Position**

Professor/Ph.D.

**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*