

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)

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+98 21 8895 4924

Email address

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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

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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