

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Study of the effectiveness of Synbiotic and Vitamin D on the Severity of Atopic Dermatitis in 1 to 24 Months Old Children

Protocol summary

Study aim

The effectiveness of synbiotic on the severity of atopic dermatitis in children 1 to 24 months The effectiveness of vitamin D on the severity of atopic dermatitis in children 1 to 24 months Comparison of the efficacy of synbiotic and vitamin D on the severity of atopic dermatitis in 1 to 24 month old children

Design

The clinical trial included two intervention groups and one control, randomized, double blind

Settings and conduct

80 patients who refer to the Haishamtahi Pediatric Clinic and have inclusion criteria are selected. All patients are examined by the physician and their severity is recorded according to SCORAD criteria. The samples are randomly divided into three groups. All patients receive routine therapies. The first group also received Padilact drops and the second group received Vitamin D. The third group only receives routine treatments for two months. After the intervention, all patients are re-examined by the same physician and the SCORAD criteria for them are calculated and recorded, and the results are compared. The examiner is unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Being 1-24 month of age Absence of any other chronic disease Having used no immunosuppressive medicines, corticosteroids and antibiotics for one week prior of the study Mother's willingness Exclusion criteria; Infectious disease receive immunosuppressive medicines, corticosteroids and antibiotics Mother's unwillingness

Intervention groups

The synbiotic group that receives 5 probiotic drops daily in addition to routine treatments The vitamin D group, which receives 1000 units of vitamin D per day in addition to routine treatments The control group receives only routine therapies including topical corticosteroids, antihistamines, and the like

Main outcome variables

Score of Atopic Dermatitis according to SCORAD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180626040248N1**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

fatemeh shamabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4441 0325

Email address

fatemeh.shamabadi@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

1988-07-11, 1367/04/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of Synbiotic and Vitamin D on the Severity of Atopic Dermatitis in 1 to 24 Months Old Children

Public title

Effectiveness of Synbiotic and Vitamin D in Atopic Dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being 1-24 month of age
Absence of any other chronic disease
Having used no immunosuppressive medicines, corticosteroids and antibiotics for one week prior of the study
Mother's willingness

Exclusion criteria:

Infectious disease
Receive immunosuppressive medicines, corticosteroids and antibiotics
Mother's unwillingness

Age

From **1 month** old to **24 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After checking the inclusion and exclusion criteria, patients are randomly (six blocks) divided into three groups which are defined by the statistic consultant by using random allocatin software

Blinding (investigator's opinion)

Triple blinded

Blinding description

The parents of patients are not known to be in the intervention or control group
The examiner, who evaluates the severity of the illness, is unaware of the type of treatment that the patient received and their group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Shohadaye hasteie Blvd.,Tohid Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.MEDSAB.REC.1397.008

Health conditions studied

1

Description of health condition studied

Atopic Dermatitis

ICD-10 code

L20-L30

ICD-10 code description

Atopic dermatitis
Excl.:circumscribed neurodermatitis (L28.0)
L20.0Besnier prurigo
L20.8Other atopic dermatitis
Eczema:flexural NEC
infantile (acute)(chronic)
intrinsic (allergic)
Neurodermatitis:atopic
diffuse
L20.9Atopic dermatitis, unspecified
L21

Primary outcomes

1

Description

Score of Atopic Dermatitis according to SCORAD

Timepoint

Beginning and end of the study (week 8)

Method of measurement

SCORAD (scoring of Atopic Dermatitis)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: In this group, patients receive 5 drops of pedilact daily for two months in addition to routine treatments . pedilact is a synbiotic (prebiotic + probiotic)

Category

Treatment - Drugs

2

Description

Intervention group2: In this group, patients receive 1,000 units of vitamin D per day for two month in addition to routine treatments.(1cc of drop vitamin D 1000iu)

Category

Treatment - Drugs

3

Description

Control group: In this group, patients receive routine treatments including topical corticosteroids, moisturizing agents, antihistamines, and ext.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatieh hospital

Full name of responsible person

Fatemeh Shamabadi

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Asadabadi Ave

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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Drghorat@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh Shamabadi

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Associate professor

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Subspecialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available