Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 viamin 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 referd 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 podiatric 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 excclusion critria, 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 dermatitisExcl.:circumscribed neurodermatitis (L28.0)L20.0Besnier prurigoL20.8Other atopic dermatitisEczema:flexural NECinfantile (acute)(chronic)intrinsic (allergic)Neurodermatitis:atopicdiffuseL20.9Atopic dermatitis, unspecifiedL21

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
Fereshteh Ghorat
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9617913114- 96179131
Phone
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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
General Practitioner
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Person responsible for scientific inquiries

Contact
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Sabzevar University of Medical Sciences
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Associate professor
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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