Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Investigation of the effect of topical probiotic lotion on atopic dermatitis in children

Protocol summary

Study aim
Determining of the effect of a probiotic lotion containing lactobacillus reuteri strain JCM 1112 on controlling the clinical symptoms of atopic dermatitis

Design
Clinical trial with control and parallel groups, double blind and randomized

Settings and conduct
This is performed on 30 patients with atopic eczema referring to the allergy clinic of Mashhad University of Medical Sciences. Patients are randomly divided into two groups of intervention and placebo. Patients in the intervention group receive a lotion containing lactobacillus reuteri strain JCM 1112 twice a day for 4 weeks for their lesions. Patients in the placebo group are treated with a lotion similar to that of the intervention group for 4 weeks. Standard eczema treatments, including skin moisturizers and topical steroids, will be performed on all patients. At the beginning and at the end of week 4, the severity of the lesions is estimated by SCORAD index. Monthly follow-up will be done up to two months later to assess the severity of the disease and the recurrence rate through SCORAD index. In this double-blind study, participants and outcome assessors are unaware of the type of grouping and medication.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Infants and children with atopic dermatitis. Exclusion criteria: Having other allergic diseases, having other skin diseases

Intervention groups
Intervention group: In this group, patients with atopic dermatitis receive a lotion containing lactobacillus reuteri strain JCM 1112 twice a day for 4 weeks for their lesions. Control group: In this group, patients with atopic dermatitis are treated with a placebo drug which looks like the one in the intervention group twice a day for 4 weeks for their lesions. Standard treatments for eczema including skin moisturizers and topical steroids, will be performed on all patients.

Main outcome variables
Severity of lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101020004976N8**
Registration date: **2021-09-08, 1400/06/17**
Registration timing: **prospective**

Last update: **2021-09-08, 1400/06/17**
Update count: **0**

Registration date
2021-09-08, 1400/06/17

Registrant information

Name
Hamid Ahanchian

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3801 2469

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ahanchianh@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-16, 1400/06/25

Expected recruitment end date
2022-02-14, 1400/11/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of topical probiotic lotion on atopic dermatitis in children

Public title

The effect of topical probiotic lotion on atopic dermatitis in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infants and children with atopic dermatitis

Exclusion criteria:

Having other allergic diseases Having other skin diseases

Age

From **1 day** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at ''www.randomization.com'' website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups control and intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are not aware of the type of treatment and the intervention. Also, outcome assessors are unaware of the grouping. Patients in the control group receive placebo drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-06-15, 1400/03/25

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.254

Health conditions studied

1

Description of health condition studied

atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes

1

Description

Severity of lesions

Timepoint

At the beginning of the study, at the end of the study in the fourth week and in the first and second months after the end of the study

Method of measurement

Severity Scoring of Atopic Dermatitis (SCORAD)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients with atopic dermatitis receive a lotion containing lactobacillus reuteri strain JCM 1112 (produced by the school of pharmacy of Mashhad University of Medical Sciences) twice a day for 4 weeks for their lesions. Standard treatments for eczema including skin moisturizers and topical steroids, will be performed on all patients.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients with atopic

dermatitis are treated with a placebo drug which is a lotion (produced by the school of pharmacy of Mashhad University of Medical Sciences) that looks like the one in the intervention group twice a day for 4 weeks for their lesions. Standard treatments for eczema including skin moisturizers and topical steroids, will be performed on all patients.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Dr Hamid Ahanchian

Street address
Pediatric Allergy department, Ghaem hospital, Ahmad Abad Blvd, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hamid Ahanchian

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Allergy

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Person responsible for scientific inquiries

Contact

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Position
Associate Professor

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data can be accessible through an email to the corresponding author.
Under which criteria data/document could be used
Data will be available for researchers in universities and other scientific institutes.
From where data/document is obtainable
After sending a request email to the corresponding author, data will be sent in 1 month.
What processes are involved for a request to access data/document
Carrying out analysis on data is permitted.
Comments