

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of Probiotic cream containing bacteria killed in children with Atopic Dermatitis.

Protocol summary

Study aim

Comparison of therapeutic effect of Probiotic ointment in the treatment of Atopic Dermatitis in children.

Design

This is a randomised, double-blind, parallel-group, controlled phase 3 study. In this study, 60 children with Atopic Dermatitis will be randomly divided into two groups of 30 in each, using Rand List software. The control group will receive Placebo ointment and the intervention group will receive Probiotic ointment.

Settings and conduct

sixty children with Atopic Dermatitis who will refer to Akbar allergy clinic will randomly be assigned into two groups of 30 subjects. Intervention group (probiotic ointment) and 30 subjects the control group (placebo ointment).

Participants/Inclusion and exclusion criteria

Inclusion criteria: children 6 months-5 years old, children with moderate to severe disease, children whose parents declare their full written informed consent to participate in this study. Exclusion criteria: children who have other skin conditions at the same time, children whose skin lesions are infected.

Intervention groups

Intervention group: probiotic ointment. In the intervention group, 30 children with Atopic Dermatitis will be treated with probiotic ointment every 12 hours for 4 weeks. Control group: topical placebo ointment. In the control group 30 children with Atopic Dermatitis will be treated with placebo ointment every 12 hours for 4 weeks.

Main outcome variables

Atopic Dermatitis lesions severity index, size of Atopic Dermatitis, patients symptoms, possible complications.

General information

Reason for update

Acronym

AD: Atopic Dermatitis

IRCT registration information

IRCT registration number: **IRCT20200117046164N1**

Registration date: **2020-04-18, 1399/01/30**

Registration timing: **prospective**

Last update: **2020-04-18, 1399/01/30**

Update count: **0**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name

Nasrin Moazzen

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3840 0000

Email address

moazzenn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-09-19, 1399/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Probiotic cream containing bacteria killed in children with Atopic Dermatitis.

Public title

Effect of the Probioti in treatment of Atopic Dermatitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with moderate to severe Disease.

Exclusion criteria:

Children who have other skin conditions at the same time. Children whose parents declare their full written informed consent to participate in this study.

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization will be carried out on an individual basis by Rand List software. The allocation will be sealed by an independent monitor and will not be broken until the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The investigator assessing outcome and analyzing the data will be blinded to treatment allocation until the end of the study.

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

Akbar Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9195933516

Approval date

2019-07-23, 1398/05/01

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.796

Health conditions studied

1

Description of health condition studied

Atopic Dermatitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Atopic Dermatitis severity index

Timepoint

Weeks 0, 2, 4

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Topical Placebu ointment. In the intervention group, 30 children with Atopic Dermatitis will be treated with Placebu ointment every 12 hours for 4 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Obtaining topical ointment containing probiotics. In the intervention group, 30 children with atopic dermatitis will receive probiotic ointment lactobacillus palntarum every 12 hours for 4 weeks. In order to prepare probiotic cream from microbial bacterial culture, microbial suspension with 108 CFU / mL concentration It is prepared and incubated in MRS culture medium for 48 hours at 37. C. This product under the AllVia® brand contains 5% by weight of probiotics in cream base. To prepare the cream, after bacterial inactivation, the bacterial precipitate is weighed and mixed with a certain amount of the cream and mixed until a cream containing 5% probiotic is finally obtained.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Dr nasrin moazzen

Street address

Akbar Hospital Kaveh street

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Mashhad

Province

Razavi Khorasan

Postal code

9195933516

Phone

+98 51 3713 3101

Email

dr.masroure@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nasrin Moazzen

Street address
Vakilabad Boulevard, facing Mellat Park, Mashhad
University of Medical Sciences
City

Mashhad

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Postal code

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Phone

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Email

dr.masroure@gmail.com

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

Dr Nasrin Moazzen

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

Street address

Fakouri Blvd, Akbar children Hospital, Mashhad

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Email

moazzenn@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nasrin Moazzen

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

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Email

moazzenn@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amir Hossein Masrour Naeimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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Email

Dr.masrour@gmail.com

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 will be shared after being unidentified.

When the data will become available and for how long

All any time

To whom data/document is available

It will be free for every one.

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Email: moazzenn@mums.ac.ir, 09151034644, Dr Nasrin Moazzen, Akbar Hospital - Kaveh sreet - Mashhad.

What processes are involved for a request to access data/document

The request will be checked, then data will be sent by Email in 1 month.

Comments