Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Effect of topical product including Lactobacillus lysate versus placebo on the clinical symptoms in the patients with atopic dermatitis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of the topical product including Lactobacillus lysate versus placebo on the clinical symptoms in the patients with atopic dermatitis

Design

This is a double-blind randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with atopic dermatitis who will refer to Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years, Atopic dermatitis for at least 6 months, Involvement of at least 20% of the body surface Exclusion criteria: Pregnancy or breastfeeding, Involvement of inguinal or genital area, Bacterial infection, Psoriasis, Immunodeficiency disorder

Intervention groups

Intervention group 1: A topical cream containing Lactobacillus rhamnosus lysate (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months Intervention group 2: A topical cream containing Lactobacillus plantarum lysate (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months Intervention group 3: A topical cream containing Lactobacillus rhamnosus lysate and Lactobacillus plantarum lysate (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months Control group: A topical cream containing placebo (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months

Main outcome variables

Primary outcome: Improvement of cutaneous symptoms of atopic dermatitis Secondary outcome: Sensitivity reaction due to topical cream

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N325**
Registration date: **2019-12-19, 1398/09/28**
Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**
Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical product including Lactobacillus lysate versus placebo on the clinical symptoms in the patients with atopic dermatitis: a double-blind randomized clinical trial

Public title

Effect of topical product including Lactobacillus lysate versus placebo on the clinical symptoms in the patients with atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 60 years, Atopic dermatitis for at least 6 months, Involvement of at least 20% of the body surface

Exclusion criteria:

Pregnancy or breastfeeding, Involvement of inguinal or genital area, Bacterial infection, Psoriasis, Immunodeficiency disorder

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.UMSHA.REC.1398.688

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

Improvement of cutaneous symptoms of atopic dermatitis

Timepoint

2 months after the intervention

Method of measurement

with clinical examination

Secondary outcomes

1

Description
Sensitivity reaction due to topical cream
Timepoint
1 and 2 months after the intervention
Method of measurement
With clinical examination

Intervention groups

1

Description
Intervention group 1: A topical cream containing Lactobacillus rhamnosus lysate (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months
Category
Treatment - Drugs

2

Description
Intervention group 2: A topical cream containing Lactobacillus plantarum lysate (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months
Category
Treatment - Drugs

3

Description
Intervention group 3: A topical cream containing Lactobacillus rhamnosus lysate and Lactobacillus plantarum lysate (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months
Category
Treatment - Drugs

4

Description
Control group: A topical cream containing placebo (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
Amir Taher Ghorbani
Street address
Sina Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3827 4184
Email
Taher2555@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Amir Taher Ghorbani
Position
Student of Pharmacy
Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

Taher2555@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Nouri

Position

Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

Fatemenouri1@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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