

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effect of oral probiotic versus placebo on the improvement of the clinical symptoms in the patients with psoriasis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral probiotics versus placebo on the improvement of the clinical symptoms in the patients with psoriasis

Design

This is a double-blind randomized clinical trial, phase II, in which 64 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with psoriasis 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. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years, Mild to moderate psoriasis, Involvement of more than 10% of the body surface Exclusion criteria: Taking probiotics in the past 6 weeks, Diabetes, Immunodeficiency disorder, Taking immunosuppressive drugs

Intervention groups

Intervention group: Topical cream corticosteroid twice daily plus oral probiotic (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 3 months Control group: Topical cream corticosteroid twice daily plus oral placebo (manufactured by the laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice a day for 3 months

Main outcome variables

Primary outcome: Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), Itching severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N323**

Registration date: **2019-12-17, 1398/09/26**

Registration timing: **prospective**

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

Registration date

2019-12-17, 1398/09/26

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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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 oral probiotic versus placebo on the improvement of the clinical symptoms in the patients with psoriasis: a double-blind randomized clinical trial

Public title

Effect of oral probiotic versus placebo on the improvement of the clinical symptoms in the patients with psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 60 years, Mild to moderate psoriasis, Involvement of more than 10% of the body surface

Exclusion criteria:

Taking probiotic in the past 6 weeks, Diabetes, Immunodeficiency disorder, Taking immunosuppressive drugs

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: **64**

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

2019-12-07, 1398/09/16

Ethics committee reference number

IR.UMSHA.REC.1398.725

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40

ICD-10 code description

Psoriasis

Primary outcomes

1

Description

Psoriasis Area and Severity Index (PASI)

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Through clinical examination

2

Description

Dermatology Life Quality Index (DLQI)

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Through clinical examination

3

Description

Itching severity

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Using Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topical cream corticosteroid twice daily plus oral probiotic (manufactured by laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice daily for 3 months

Category

Treatment - Drugs

2

Description

Control group: Topical cream corticosteroid twice daily plus oral placebo (manufactured by laboratory of School of Pharmacy Hamadan University of Medical Sciences) twice a day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Ali Akbarzadeh

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

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

Ali Akbarzadeh

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Ph.D.

Other areas of specialty/work

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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

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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

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