Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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
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Sponsors / Funding sources

1

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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
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Ali Akbarzadeh
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Student of Pharmacy
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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
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