Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the effect of oral administration of probiotic strains with placebo on the clinical severity of psoriasis vulgaris

Protocol summary

Study aim
Determination of the effect of oral administration of probiotic strains in the treatment of psoriasis

Design
Phase 3, parallel group, clinical trial, with consecutive sampling, including 60 patients, single blinded, computerized randomized with permuted blocks

Settings and conduct
The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences with the daily consumption of probiotic capsules and topical mometasone in the intervention group, and daily consumption of placebo capsules and topical mometasone in the control group. The patients are assessed at the beginning of treatment, months 1, 2, and 3 by Psoriasis Area Severity Index (PASI) score. The patients and outcome assessors are blind to the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Plaque type psoriasis; 18 years of age or older; Involvement of 20% or less of body surface area Exclusion criteria: Severe scalp psoriasis; Worsening of signs and symptoms of psoriasis during treatment; Pregnancy; Lactation; Consumption of any systemic treatment affecting psoriasis within the last three months , Antibiotic administration within the recent two weeks; Any signs and symptoms of bacterial infections; Concomitant skin diseases; Presence of significant liver diseases; Presence of significant chronic kidney diseases; Consumption of probiotic-containing products

Intervention groups
Intervention group: Daily consumption of Lactocare probiotic capsules (Zist takhmir company, Tehran, Iran), the once daily application of mometasone ointment on skin lesions and mometasone lotion on the scalp lesions for 3 months Control group: Daily consumption of placebo capsules containing starch, once daily application of mometasone ointment on skin lesions and mometasone lotion on the scalp lesions for 3 months

Main outcome variables
Quantitative score of the clinical severity of psoriasis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140212016557N8**
Registration date: **2021-10-03, 1400/07/11**
Registration timing: **prospective**

Last update: **2021-10-03, 1400/07/11**
Update count: **0**

Registration date
2021-10-03, 1400/07/11

Registrant information

Name
Mozhdeh Sepaskhah

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 712125239

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sepaskhah@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral administration of probiotic strains with placebo on the clinical severity of psoriasis vulgaris

Public title

Effect of oral probiotic in the treatment of psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Plaque type psoriasis 18 years of age or older Involvement of 20% or less of body surface area

Exclusion criteria:

Severe scalp psoriasis Worsening of signs and symptoms of psoriasis during treatment Pregnancy Lactation Consumption of any systemic treatment affecting psoriasis within the last three months before recruiting in the study Antibiotic administration within the recent two weeks Any signs and symptoms of bacterial infections Concomitant skin diseases Presence of significant liver diseases Presence of significant chronic kidney diseases Consumption of probiotic-containing products (including probiotic-containing foods)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software. The output of software is a table that determines the patient receives probiotic or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Probiotic and placebo are packed in the similar packages and are numbered according the patients' codes. Investigator and care provider are aware of the types pf drugs. But, data collectors and outcome assessors are not aware of the medication of each patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2021-09-08, 1400/06/17

Ethics committee reference number

IR.SUMS.MED.REC.1400.284

Health conditions studied

1

Description of health condition studied

psoriasis

ICD-10 code

L40.0

ICD-10 code description

psoriasis vulgaris

Primary outcomes

1

Description

Quantitative score of the clinical severity of psoriasis

Timepoint

At the beginning of treatment, months 1, 2, and 3 after treatment

Method of measurement

Psoriasis Area Severity Index (PASI) score

Secondary outcomes

1

Description

Qualitative clinical severity of psoriasis

Timepoint

Months 1, 2, and 3 after treatment

Method of measurement

Physician global assessment score

2

Description
Quality of life
Timepoint
At the beginning and end of treatment
Method of measurement
Dermatology quality of life index questionnaire

3

Description
Percentage of acceptable improvement
Timepoint
Months 1, 2, and 3 after treatment
Method of measurement
Percentage of people who achieve equal to or more than ٧٥% reduction in Psoriasis Area Severity Score

4

Description
Rate of improvement
Timepoint
Months 1, 2, and 3 after treatment
Method of measurement
Time of achievement of equal to or more than ٧٥% reduction in Psoriasis Area Severity Score

Intervention groups

1

Description
Intervention group: Daily consumption of Lactocare probiotic capsules (Zist takhmir company, Tehran, Iran), the once daily application of mometasone ointment on skin lesions and mometasone lotion on the scalp lesions for 3 months
Category
Treatment - Drugs

2

Description
Control group: Daily consumption of placebo capsules containing starch, once daily application of mometasone ointment on skin lesions and mometasone lotion on the scalp lesions for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic, Shahid Faghihi hospital
Full name of responsible person
Mozhdeh Sepaskhah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Abbas Rezaianzade
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Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
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Grant name
Research grant of the Research Council of Shiraz University of Medical Sciences
Grant code / Reference number
22635
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Amir Nasiri

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable