

# 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

##### Email address

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 of 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 70% 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 70% 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

##### **Street address**

Dermatology clinic, Faghihi hospital, Zand St.

#### **City**

Shiraz

#### **Province**

Fars

#### **Postal code**

7134844119

#### **Phone**

+98 71 3212 5239

#### **Email**

sepaskhah@sums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Abbas Rezaianzade

##### **Street address**

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

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7134814336

##### **Phone**

+98 71 3235 7282

##### **Email**

vcrdep@sums.ac.ir

#### **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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amir\_nasiri68@yahoo.com

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Mozhdeh Sepaskhah

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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sepaskhah@sums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mozhdeh Sepaskhah

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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**Email**

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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