Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral probiotics on population, receptor expression, and related cytokines of T and B cells subsets in psoriasis patients

Protocol summary

Study aim
Evaluation of the effect of oral probiotics on population, receptor expression, and related cytokines of T and B cells subsets in psoriasis patients

Design
Randomized, double-blind, phase 2, placebo-controlled clinical trial in 40 patients

Settings and conduct
Patients with moderate to severe psoriasis are selected by physician by referring them to a specialized rheumatology clinic, and a blood sample is taken from the patients after taking a three-month period of probiotic tablets to check the severity of the disease. Moreover, the population and expression levels of TH1, TH2, B cells, TH17, and Treg cells in the patient's blood samples are evaluated by flow cytometry. In this study, Blinding will be performed for patients, physician, and experimenter.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 18 to 65 years old; signing the informed consent form; patients with the diagnosis of moderate to severe psoriasis based on Psoriasis Area and Severity Index(PASI score). Exclusion criteria: pregnancy or lactation; suffering from other autoimmune diseases and inflammation disease; suffering from cirrhosis and hepatic disease; suffering from metabolic syndrome; suffering from severe renal disease; the consumption of antibiotics and any kind of probiotics 2 weeks ago; worsening of signs and symptoms of psoriasis during treatment.

Intervention groups
Intervention Group: Psoriasis patients consume one probiotic LactoCare tablet (Zist Takhmir company) orally for three months and then blood samples are examined. Control Group: Patients consume a LactoCare placebo tablet daily(the packaging and color are similar to the LactoCare tablet) for three months and then their blood samples will be examined.

Main outcome variables
The population and expression levels receptors of TH1, TH2, B cells, TH17, and Treg by flowcytometry

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221213056802N1**
Registration date: **2023-03-01, 1401/12/10**
Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**
Update count: **0**

Registration date
2023-03-01, 1401/12/10

Registrant information

Name
Seyed-Alireza Esmaili

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3800 2379

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esmaeiliar@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-19, 1402/01/30

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral probiotics on population, receptor expression, and related cytokines of T and B cells subsets in psoriasis patients

Public title

The effect of oral probiotic(LactoCare) on psoriasis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years Signing the informed consent form Patients with the diagnosis of the moderate to severe psoriasis based on Psoriasis Area and Severity Index(PASI score)

Exclusion criteria:

Pregnant or lactation Suffering from other autoimmune disease and inflammation disease Suffering from cirrhosis and hepatic disease Suffering from metabolic syndrome Suffering from severe renal disease The consumption of antibiotics and any kind of probiotics 2 weeks ago Worsening of signs and symptoms of psoriasis during treatment

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

By using random number generation software, a set of numbers from 1 to 40 will be generated randomly. These numbers are given to the patients in the form of a sealed envelope, and then the patients with odd numbers receive the odd-labeled intervention, and the patients with even numbers receive the even-labeled intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants have been blinded by supplementation of probiotic and placebo in similar packaging, shape, and color. Investigator and physician have also been blinded in terms of prescribing two types of intervention (probiotic and placebo were considered as odd and even-labeled interventions) through numbers obtained by random allocation software that would be done by one colleague.

Placebo

Used

Assignment

Parallel

Other design features

Following three months of taking the probiotic tablets, 10 cc of whole blood will be collected from both groups of patients (treatment and placebo) and the population of lymphocyte cells will be checked.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University Of Medical Science

Street address

Immunology department, School of Medicine, Kalantary street, Mashhad University of Medical Science

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-03-02, 1400/12/11

Ethics committee reference number

Ir.mums.medical.rec.1401.321

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

The population of TH1

Timepoint

3 months later the consumption of oral probiotics

Method of measurement

Flowcytometry

2

Description
The population of TH2
Timepoint
3 months later the consumption of oral probiotics
Method of measurement
Flowcytometry

3

Description
The population of Treg
Timepoint
3 months later the consumption of oral probiotics
Method of measurement
Flowcytometry

4

Description
The population of B cells
Timepoint
3 months later the consumption of oral probiotics
Method of measurement
Flowcytometry

5

Description
The population of TH17
Timepoint
3 months later the consumption of oral probiotics
Method of measurement
Flowcytometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients are instructed to consume orally one LactoCare probiotic tablet(zist takhmir, Iran) daily for 3 months
Category
Treatment - Drugs

2

Description
Control group: patients are instructed to consume orally one LactoCare probiotic placebo tablet(zist takhmir, Iran) daily for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bozorgmehr medical building
Full name of responsible person
Zahrz Rezaie Yazdi
Street address
Bozorgmehr medical building, second Mohtashami, Aref street 1, Ahmad Abad avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hanieh Kolahdooz Ghuchani

Position
Research assistance

Latest degree
Master

Other areas of specialty/work
Immunology

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Person responsible for scientific inquiries

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Assistance professor

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Ph.D.

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Immunology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available