Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Probiotic Supplementation Containing Lactobacillus & Bifidobacterium Species on the Inflammatory and Oxidative Markers and Some Clinical Parameters in Patients with Psoriasis

Protocol summary

Study aim

Determination of effect of 60 days intervention with Lactobacillus and Bifidobacterium probiotic supplements on inflammatory and oxidative indices and some clinical indicators in patients with psoriasis compared to control group

Design

A double-blind randomized controlled clinical trial

Settings and conduct

This study will be performed in 44 patients with psoriasis for 60 days. Eligible patients from among patients referring to three different socio-economic health centers in Tabriz University of Medical Sciences will enter the study based on entry and failure criteria after obtaining informed written consent. Subjects are then assigned to two groups (intervention & placebo).The general health questionnaire, validated appetite assessment questionnaire, physical activity questionnaire, anthropometric measurements (waist circumference, hip circumference, height and weight for BMI calculation), and blood pressure measurements for each person will be completed. In order to measure the serum levels of metabolic parameters (TC, TG, HDL-C, LDL-C, FBS & insulin) as well as serum levels of inflammatory indices (hs-CRP and LPS) and oxidative indices (MDA & TAC) at baseline and at the end of the study in subjects with fasting (after 12-10 hours of fasting) blood sampling (5 ml) will be done. Incidentally, dietary intake of the subjects will be evaluated by a 3-day food record questionnaire.

Participants/Inclusion and exclusion criteria

Participants: Women & Men 18 to 50 years old with psoriasis

Intervention groups

Intervention Group: 2 capsules containing probiotic supplement (Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium lactis and Bifidobacterium langum) daily. Control Group: 2 placebo capsules containing starch per day.

Main outcome variables

1)Inflammatory Markers' Levels (hs-CRP & LPS), 2)Oxidative Markers' Levels (MDA & TAC), 3)Scores of SF-36, PASI & BDI-II Questionnaires

General information

Reason for update

Due to the start of sampling on 28 March 2020, the expected start and end date of sampling was updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191124045483N1**
Registration date: **2020-03-20, 1399/01/01**
Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**
Update count: **1**

Registration date

2020-03-20, 1399/01/01

Registrant information

Name
amir mehdi iranshahi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3335 5921
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iranshahi.nutrition@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-28, 1399/01/09

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Probiotic Supplementation Containing Lactobacillus & Bifidobacterium Species on the Inflammatory and Oxidative Markers and Some Clinical Parameters in Patients with Psoriasis

Public title

The Effect of Probiotic Supplementation on the Inflammatory and Oxidative Markers and Some Clinical Parameters in Patients with Psoriasis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the diagnosis of the medium to severe psoriasis are based on the classification criteria for Psoriasis vulgaris. Patients aged between 18 and 50 (until the date of screening) The inclusion of participants in the study is informed by the understanding of all the procedures of the study, voluntary contributions and signed consent form.

Exclusion criteria:

Pregnant women, prior to pregnancy or lactation The existence and history of conditions or serious wounds in the heart, lungs, kidney and other vital organs and the endocrine system. Also patients with respiratory and cancer disorders, tuberculosis and HIV infections. patients with chronic diarrhea or peptic ulcer up to one year patients suffering from malignancy or tumor patients with acute and chronic infectious diseases Patients with psychiatric disorders, alcohol and drug abuse Patients who refuse to participate in the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Selected individuals will be randomly allocated to 2 intervention groups (probiotic)and control group (placebo after obtaining written consent by using random blocking method (4 and 8 blocks) and RAS software (Random Allocation Software) and allocation ratio of 1: 1.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants have been blinded by supplementation of probiotic and placebo in packaging, shape, color and smell alike. Investigators have also been blinded in terms of prescribing two types of intervention (probiotic or placebo with number of intervention 1 or 2) through numbers obtained by random allocation software.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research Vice-chancellor of Tabriz University of Medical Sciences., End of Golgasht Ave., Tabriz., Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-11-25, 1398/09/04

Ethics committee reference number

IR.TBZMED.REC.1398.916

Health conditions studied

1

Description of health condition studied

Participants are patients with psoriasis. Psoriasis is a skin condition that appears in the form of thick white-silver skins and itchy plaques on the surface of the skin.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Metabolic parameters [serum glucose and insulin levels, HOMA-IR and lipid profile (Triglyceride، Total cholesterol، LDL- cholesterol و HDL- cholesterol)] in both study groups.

Timepoint

Metabolic parameters measurement [serum glucose and insulin levels, HOMA-IR and lipid profile (Triglyceride، Total cholesterol، LDL- cholesterol و HDL- cholesterol)] at baseline and 8 weeks (end of study) in both study groups.

Method of measurement

Calorimetric methods (ELISA, spectrophotometry, autoanalyzer)

2

Description

Systolic and diastolic blood pressure and anthropometric indices (weight, Body Mass Index, waist circumference, hip circumference and Waist to Hip Ratio) in both study groups.

Timepoint

Measurement of systolic and diastolic blood pressure and anthropometric indices (weight, Body Mass Index, waist circumference, hip circumference and Waist to Hip Ratio) at baseline and 8 weeks (end of study) in both study groups.

Method of measurement

A mercury barometer will be used to measure systolic and diastolic blood pressure, and digital scales, gauges and tape meters will be used for anthropometric measurements.

3

Description

Levels of inflammatory biomarkers (Lipopolysaccharide and high sensitivity -CRP) in both study groups.

Timepoint

Measurement of levels of inflammatory markers (Lipopolysaccharide and high sensitivity -CRP) at baseline and 8 weeks later (end of study) in both study groups.

Method of measurement

Calorimetric methods (ELISA, spectrophotometry, autoanalyzer)

4

Description

Levels of oxidative indices (Total Antioxidant Capacity and Malondialdehyde) in both study groups.

Timepoint

Measurement of oxidative index levels (Total Antioxidant Capacity and Malondialdehyde) at baseline and 8 weeks (end of study) in both study groups.

Method of measurement

Calorimetric methods (ELISA, spectrophotometry, autoanalyzer)

5

Description

Clinical parameters (Health related quality of life questionnaire or SF-36, PASI or Psoriasis area and severity index and BDI-II or Beck Depression Inventory 2) in both study groups.

Timepoint

Assessment of Clinical parameters (Health related quality of life questionnaire or SF-36, PASI or Psoriasis area and severity index and BDI-II or Beck Depression Inventory 2) at baseline and 8 weeks (end of study) in both study groups.

Method of measurement

Questionnaires SF-36, PASI and BDI-II

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Will intake 2 capsules orally in a day that containing probiotic supplements at least 1.6× 109 cfu/g of probiotics including (Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium lactis and Bifidobacterium langum) for 8 weeks, which were prepared by ZIST TAKGENE Co.

Category

Treatment - Other

2

Description

Control group: Will intake 2 placebo capsules daily for 8 weeks. Placebo capsules containing starch that are similar in taste, color and odor to probiotic capsules and were prepared by ZIST TAKGENE Co.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Health Centers

Full name of responsible person

Dr. Mitra Yeganeh

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tabriz 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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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

Title and more details about the data/document

Requested data will be provided to researchers for statistical analysis of the submitted proposal (meta-analysis).

When the data will become available and for how long

Starting immediately after publication

To whom data/document is available

Data will be available to researchers as well as journals.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of a proposal to perform meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journals for checking.

From where data/document is obtainable

Refer to the email address (farshbafa@tbzmed.ac.ir)

What processes are involved for a request to access data/document

The requests will be sent by email and data will be available within a week.

Comments