# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## Comparison of the efficacy of probiotic supplement in inflammatory markers, metabolic parameters and some clinical parameters in patients with psoriasis

## Protocol summary

**Study aim**
The aim of the present study was to evaluate the effect of probiotic supplementation on the level of inflammatory factors in psoriasis patients.

**Design**
Randomized double-blind clinical trial with two arm parallel groups

**Settings and conduct**
The trial will be conducted at the Sheikh al-Rays Clinic affiliated to Tabriz University of Medical Sciences. All patients will be screened for eligibility by a dermatologist. Individuals who are willing to participate in the study will be evaluated to meet the inclusion criteria. They are then asked to complete an informed consent form. A third party blind to the study will deliver sequences extracted from the random allocation software. After nocturnal fasting, blood samples will be collected and supplements delivered to participants. The duration of the supplementary period will be 8 weeks.

**Participants/Inclusion and exclusion criteria**
Forty four patients with psoriasis will be included in the study. Subjects with chronic renal failure and history of supplementation with probiotics will not be included.

**Intervention groups**
Intervention group: Patients in this group will receive probiotic supplements for 8 weeks. Probiotic supplement is a capsule containing multi-strain probiotic with at least 1.8× 10 9 colony forming units (CFU) (a product by TakZist Gene Co.and made in The Iran) and used once a day with lunch. To ensure supplement consumption, patients will be contacted weekly. Control group: participants will be instructed to take one capsules daily, each contains of maltodextrin as placebo for 8 weeks. Placebo capsules are completely similar to probiotic capsules so that they are hardly distinguished from each other (they are made by TAKGENE ZIST pharmaceutical company).

**Main outcome variables**
Serum Levels of Inflammatory Factors (Interleukin 6 and 10)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180712040438N2**
Registration date: **2020-01-10, 1398/10/20**
Registration timing: **retrospective**

Last update: **2020-01-10, 1398/10/20**
Update count: **0**

**Registration date**
2020-01-10, 1398/10/20

**Registrant information**

**Name**
Jalal Moludi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 41 3335 2148

**Email address**
jmoludi@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-08-11, 1398/05/20

**Expected recruitment end date**
2019-11-22, 1398/09/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the efficacy of probiotic supplement in inflammatory markers, metabolic parameters and some clinical parameters in patients with psoriasis

**Public title**
Effect of probiotic supplement in treatment of psoriasis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
diagnosed with psoriasis Subjects aged 15-50 years
**Exclusion criteria:**
patient with chronic renal failure; hemodialysis receiving immunosuppressive, anti-inflammatory and corticosteroid drugs history of supplementation with pre/pro/symbiotic or antioxidants during previous two months
**Age**
From **18 years** old to **50 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **44**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
From among the patients who volunteer to participate in the study, 44 individuals will be selected by simple randomization. Then by using the Random Allocation Software, the subjects will be allocated into either probiotic or placebo group, stratified by sex and age. The sequence of randomization will be kept in a safe place by an independent party and is not aware of the study.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this double-blind study, no patient and investigator will be aware of the treatment assignments for the duration of the study. For blinding the trial, the Probiotic Capsule and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company (Takgene Zist Company)
**Placebo**
Used
**Assignment**
Parallel
**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**
Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**Approval date**
2019-07-31, 1398/05/09
**Ethics committee reference number**
IR.TBZMED.REC.1398.504

## 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**
Interleukin 6 Level
**Timepoint**
Baseline and 2 months after intervention
**Method of measurement**
via ELISA kit

### 2

**Description**
Interleukin 10 Level
**Timepoint**
Baseline and 2 months after intervention
**Method of measurement**
via ELISA kit

### 3

**Description**
total cholesterol
**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

spectrophotometry

**4**

**Description**

triglycerides

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

spectrophotometry

**5**

**Description**

high density lipoprotein

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

spectrophotometry

**6**

**Description**

low density lipoprotein

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

Formula

**7**

**Description**

Fasting Blood Sugar

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

Enzymatic

**8**

**Description**

Weight

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

scale

**9**

**Description**

Body Mass Index

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

formula

**10**

**Description**

Hip Circumfrance

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

meter

**11**

**Description**

Waist Circumfrance

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

meter

**12**

**Description**

Dermatology Life Quality Index (DLQI) score

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

Dermatology Life Quality Index questionnaire

**13**

**Description**

Psoriasis Area Severity Index (PASI) score

**Timepoint**

Baseline and 2 months after intervention

**Method of measurement**

Psoriasis Area and Severity Index questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Patients in this group will receive probiotic supplements for 8 weeks. Probiotic supplement is a capsule containing multi-strain probiotic with at least 1.8× 10 9 colony forming units (CFU) (a product by TakZist Gene Co.and made in The Iran) and used once a day with lunch.

**Category**

Treatment - Drugs

**2**

**Description**

control group: participants will be instructed to take two capsules daily, each contains of starch as placebo for 8 weeks. Placebo capsules are completely similar to probiotic capsules so that they are hardly distinguished from each other (they are made by TAKGENE ZIST pharmaceutical company). We will contact the patients weekly to ensure that participants would act in compliance with the protocol of study, and remind them to take their capsules daily.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Sheikh Al-Rais Clinic
**Full name of responsible person**
Dr. Armaghan Ghareaghaji Zare
**Street address**
Sheikh Al Rais Building - Azadi Street
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**Phone**
+98 41 3335 2148
**Fax**
**Email**
Armaghan.g.zare@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. Abolghasem Jouyban
**Street address**
Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**Phone**
+98 41 3335 7581
**Fax**
+98 41 3334 0634
**Email**
Ajouyban@hotmail.com

**Grant name**
*empty*
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**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**
Tabriz University of Medical Sciences
**Full name of responsible person**
Jalal Moludi
**Position**
PhD Candidate
**Latest degree**
Master
**Other areas of specialty/work**
Nutrition
**Street address**
Tabriz University of Medical Science, Nutrition Faculty, Attar Neyshabori, Goldasht street, Tabriz, Iran
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**Phone**
+98 41 3335 2148
**Fax**
+98 41 3335 2148
**Email**
Moludij@tbzmed.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Jalal Moludi
**Position**
PhD Candidate
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Faculty of Nutrition , Attar Neishabouri Avenue, Golgasht street,Tabriz, Postal Code: 5166614711
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614711
**Phone**
+98 41 3335 2148
**Fax**
+98 41 3335 2148

**Email**
moludij@tbzmed.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Jalal Moludi

**Position**
PhD Candidate

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nutrition

**Street address**
Faculty of Nutrition , Attar Neishabouri Avenue, Golgasht street,Tabriz, Postal Code: 5166614711

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5166614711

**Phone**
+98 41 3335 2148

**Email**
jmoludi@yahoo.com

## 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**
Yes - There is 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**
Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**
Data collected for the primary outcomes will be shared

**When the data will become available and for how long**
Accessibility to data is possible 8 months after publication.

**To whom data/document is available**
The data will only be available for people working in academic institutions.

**Under which criteria data/document could be used**
The data of the present study will only be accessible by other researchers, for conducting Meta analysis

**From where data/document is obtainable**
Jalal Moludi, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, +989399516760, jmoludi@yahoo.com

**What processes are involved for a request to access data/document**
Any one who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All these steps will not take more than 10 days.

**Comments**