

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Prebiotics on Menopausal Symptoms and Metabolic Indicators in Postmenopausal Women: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

To determine the effect of peribiotic on menopausal symptoms and metabolic indices in menopausal women

##### Design

Triple-blind, randomized, control clinical trial

##### Settings and conduct

This trial will be performed on 60 menopausal women who referring to health centers of Tabriz. Menopausal women will be assessed according to the eligibility criteria and if they have criteria and willingness to participate in the study, the written informed consent will be obtained and primary evaluations will be conducted. Participants will be assigned into two groups of peribiotic and placebo using block randomization method with block sizes of 4 and 6 and allocation ratio of 1:1.

##### Participants/Inclusion and exclusion criteria

The participants will be healthy and married menopausal women ages 40 to 60 years who have hot flashes at least twice a week.

##### Intervention groups

The intervention group will receive one pocket of 20 gram peribiotic that will use in the glass of water daily for two months. Also, the control group will receive one pocket of 20 gram placebo that will use in the glass of water daily for two months.

##### Main outcome variables

The main outcomes include menopausal symptoms and metabolic indices (serum levels of insulin, fasting blood sugar, and lipid profiles).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120718010324N52**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

##### Registration date

2019-12-04, 1398/09/13

##### Registrant information

###### Name

Mojgan Mirghafourvand

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6969

###### Email address

mirghafourvandm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-30, 1398/09/09

##### Expected recruitment end date

2020-03-18, 1398/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Prebiotics on Menopausal Symptoms and Metabolic Indicators in Postmenopausal Women: A Randomized Clinical Trial

##### Public title

The Effect of Prebiotics on Menopausal Symptoms and Metabolic Indicators in Postmenopausal Women

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willingness to participate in the study Having sufficient literacy to complete the questionnaire or the presence of a literate person in the family Natural menopause Being married Women who have been passed lower than 6 years from menopause. Having at least 40 years and a maximum of 60 Having hot flashes at least twice a week Not taking of probiotic, periotics, vitamins, minerals, and omega-3 during the study and three months before the intervention

### Exclusion criteria:

Use of tobacco, alcohol and herbal medicines Stressful factors such as the death of first-degree relatives in the last 6 months and the loss of a job Known psychiatric or systemic problems including cardiovascular, digestive tract, liver, blood and endocrine diseases, and ..... Taking of any effective medicines for hot flashes (clonidine, methyl dopa, gabapentin, selective serotonin reuptake inhibitors (SSRIs), norepinephrine inhibitors (SNRIs) and soy isoflavones The presence of factors causing vasomotor disorder, such as thyroid disease, according to the participant expression Use of food supplements Extreme physical activity (an activity that can not be easily talked about by an individual due to increased breathing and breathing).

## Age

From **40 years** old to **60 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using block randomization method with block sizes of 4 and 6 and allocation ratio of 1:1 using Randomiser software

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Participants, researcher, data analyst, and outcome assessors will be blinded due to the fact that the medications will be packaged in sealed envelopes and random allocation will be conducted by a person not involved in the study.

## 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

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947977

#### Approval date

2019-04-07, 1398/01/18

#### Ethics committee reference number

IR.TBZMED.REC.1398.016

## Health conditions studied

### 1

#### Description of health condition studied

Menopausal symptoms

#### ICD-10 code

N95.1

#### ICD-10 code description

Menopausal and female climacteric states

## Primary outcomes

### 1

#### Description

Serum levels of metabolic indices (Insulin, fasting blood sugar and Lipid profile)

#### Timepoint

Before intervention and two months after starting the intervention

#### Method of measurement

Blood tests

### 2

#### Description

The total score of menopausal symptoms and its subscales

#### Timepoint

Before intervention and two months after starting the intervention

#### Method of measurement

Greene scale

## Secondary outcomes

### 1

#### Description

Hot flashes number

#### Timepoint

Before intervention and two months after starting the intervention

#### Method of measurement

Checklist

### 2

#### Description

Anthropometric indices (Waist circumference, hip circumference and body mass index)

#### Timepoint

Before intervention and two months after starting the intervention

#### Method of measurement

Measuring with centimeter and scale

### 3

#### Description

The frequency of side effects

#### Timepoint

During the study

#### Method of measurement

Checklist

## Intervention groups

### 1

#### Description

The intervention group will receive one packet of 20 gram probiotic that will use in the glass of water daily for two months.

#### Category

Treatment - Drugs

### 2

#### Description

The control group will receive one packet of 20 gram placebo (Maltodextrin) that will use in the glass of water daily for two months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Talegani hospital

##### Full name of responsible person

Sevda Gholizadeh Shamasbi

##### Street address

Talegani hospital, Rah Ahan square, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5197615413

##### Phone

+98 41 3442 4425

##### Email

s.gholizadeh7007@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Samiei

##### Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947977

##### Phone

+98 41 3479 6770

##### Fax

+98 41 3479 6969

##### Email

mirghafourvandm@tbzmed.ac.ir

#### 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Sevda Gholizadeh shamasbi

**Position**

Masters of Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Faculty of Nursing & Midwifery, South Shariati Street

**City**

Tabriz

**Province**

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**Postal code**

5138947977

**Phone**

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**Email**

s.gholizadeh7007@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mojgan Mirghafourvand

**Position**

PhD of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mojgan Mirghafourvand

**Position**

PhD of Reproductive Health

**Latest degree**

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**Email**

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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**

Participants data is confidential

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The results of clinical study will be published as article.

**When the data will become available and for how long**

Immediately after publishing the results.

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Scientific using with citation to article

**From where data/document is obtainable**

Email: mirghafourvandm@tbzmed.ac.ir

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

Up to one week after communication by email

**Comments**