Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 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 perbiotic 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, peribiotics, 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 pocket of 20 gram perbiotic that will use in the glass of water daily for two months.
Category
Treatment - Drugs

2

Description
The control group will receive one pocket 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
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Fax
+98 41 3479 6969
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
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
mirghafourvandm@tbzmed.ac.ir

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
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
mirghafourvandm@tbzmed.ac.ir

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