Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of probiotic administration on severity of the menopausal symptoms and mental health of the menopausal women

Protocol summary

Study aim
The effect of probiotic administration on severity of the menopausal symptoms and mental health of the menopausal women

Design
Clinical trial with control group, with parallel groups, triple blind, randomized

Settings and conduct
Participants are randomly assigned to the two groups of 45 recipients of Probiotic capsule and placebo group.This study will be conducted in Comprehensive Health Centers of Hamadan city. In this study, neither the researcher, nor the menopausal women and nor the analyzer knows the contents of the package and triple blinded will be performed. In intervention group, Probiotic capsule and in Control group, placebo will be prescribed Once a day for 6 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 45-55, having menopause symptoms; not using cigarette or alcohol, not having physical or mental diseases, not using of relaxation techniques, not using of hormonal or herbal therapies Exclusion criteria: irregular use of the drug, refuse from continuing to participate in study

Intervention groups
Intervention group: Probiotic supplement will be prescribed in the form of Oral Capsule 200 mg, Once a day for 6 weeks. This drug Will be Producted by Hamadan University of Medical Sciences. Control group: placebo will be prescribed in the form of Oral Capsule contain ỏf Starch 200 mg Once a day for 6 weeks. The placebo is made in Hamadan University of Medical Sciences

Main outcome variables
Severity of menopause symptoms Stress-anxiety-depression

General information

Reason for update
Having menopause symptoms

Acronym

IRCT registration information
IRCT registration number: **IRCT20180707040370N9**
Registration date: **2023-01-19, 1401/10/29**
Registration timing: **prospective**

Last update: **2024-08-16, 1403/05/26**
Update count: **2**

Registration date
2023-01-19, 1401/10/29

Registrant information

Name
Ensiyeh Jenabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0496

Email address
e.jenabi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of probiotic administration on severity of the menopausal symptoms and mental health of the menopausal women

Public title
The effect of probiotic administration on severity of the menopausal symptoms and mental health

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 45-55 not using cigarette or alcohol not having physical or mental diseases not using of relaxation techniques not using of hormonal or herbal therapies at least 1 to 5 years have passed since menopause Having menopause symptoms

Exclusion criteria:
irregular use of the drug refuse from continuing to participate in study

Age
From **45 years** old to **55 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are randomly selected by random.org computer program that are assigned to the two groups of 45 recipients of capsule Probiotic and placebo. The allocation of the participants to the groups is performed by method of allocation concealment. In this way, using the random block 4, the allocation sequence is specified. Then, in the sealed envelopes, the intervention name is written in sequential order, and is numbered accordingly

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug packages are similar and were given to menopausal women by other person. This person does not inform about the package contents. Therefore, neither the researcher, nor the menopausal women and nor the analyzer knows the contents of the package and triple blinding will be performed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Fahmiheh Street, Hamadan

City
Hamadan

Province
Hamadan

Postal code
6517838678

Approval date
2023-01-18, 1401/10/28

Ethics committee reference number
IR.UMSHA.REC.1401.887

Health conditions studied

1

Description of health condition studied
Severity of the Menopausal Symptoms and Mental health

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Severity of menopause symptoms

Timepoint
Before the intervention, 3 and 6 weeks after the intervention

Method of measurement
MRS scale

2

Description
Stress

Timepoint
Before the intervention, 3 and 6 weeks after the intervention

Method of measurement
Questionnaire DASS-21

3

Description
anxiety

Timepoint
Before the intervention, 3 and 6 weeks after the intervention

Method of measurement
Questionnaire DASS-21

4

Description
depression
Timepoint
Before the intervention, 3 and 6 weeks after the intervention
Method of measurement
Questionnaire DASS-21

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Probiotic supplement will be prescribed in the form of Oral Capsule 200 mg, Once a day for 6 weeks. Including Lactobacillus plantarum, Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus bulgaricus, Bifidobacterium infantis, Bifidobacterium longum, Bifidobacterium breve and Streptococcus thermophilus.This drug Will be Producted by Hamadan University of Medical Sciences
Category
Treatment - Drugs

2

Description
Control group: placebo will be prescribed in the form of Oral Capsule contain ỗf Starch 200 mg Once a day for 6 weeks. The placebo is made in Hamadan University of Medical Sciences
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Service Center of Shohada
Full name of responsible person
Ensiyeh Jenabi
Street address
Comprehensive Health Service Center of Shohada., Takhti Ave., Hamadan
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6517838344
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+98 81 3252 4321
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Shohada.health@yahoo.com

2

Recruitment center
Name of recruitment center
Comprehensive Health Service Center of Khezr
Full name of responsible person
Ensiyeh Jenabi
Street address
Comprehensive Health Service Center of Khezr., Khezr Ave., Hamadan
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Hamadan
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6517838289
Phone
+98 81 3266 0550
Email
Khezr.Health@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeid Bashirian
Street address
Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Av
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6517838695
Phone
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S_bashrian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
En Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Ensiyeh Jenabi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ensiyeh Jenabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Data analysis is permitted with the author's permission.

From where data/document is obtainable

Hamadan ،Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave Responsible person: Ensiyeh Jenabi Postal code: 6517838695 Phone number: +98 81 3838 0496 Email: en.jenabi@yahoo.com

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

Requests should be submitted to the corresponding author via email. He will follow up with the inquiry

Comments