Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of probiotic consumption on fatigue and sexual function in postmenopausal women

Protocol summary

Study aim
The effect of probiotic consumption on fatigue and sexual function in postmenopausal women
Design
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.
Settings and conduct
comprehensive health centers in Hamedan city
Participants/Inclusion and exclusion 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
Intervention groups
Intervention group: Probiotic supplement will be prescribed in the form of Oral Capsule 200 mg, Once a day for 6 weeks. Including Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus rhamnusos,Bifidobacterium Lactis, Bifidobacterium longum, Bifidobacterium breve and with dose CFU 3×109.This drug Will be Producted by Company of Zist Takhmir.
Main outcome variables
Fatigue severity; Sexual function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180707040370N11**
Registration date: **2024-08-16, 1403/05/26**
Registration timing: **prospective**

Last update: **2024-08-16, 1403/05/26**
Update count: **0**
Registration date
2024-08-16, 1403/05/26

Registrant information
Name
Ensiyeh Jenabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 81 3838 0496
Email address
e.jenabi@umsha.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-05, 1403/06/15
Expected recruitment end date
2024-12-05, 1403/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotic consumption on fatigue and sexual function in postmenopausal women

Public title
The effect of probiotic consumption on fatigue and sexual function in postmenopausal women
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

Exclusion criteria:

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly selected by random.org computer program that are assigned to the two groups of 40 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 the analyzer knows the contents of the package and double triple blinding will be performed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی همدان

Street address

Hamadan University of Medical Sciences, Fahmiheh Street, Hamadan

City

همدان

Province

Hamadan

Postal code

6517838678

Approval date

2024-08-03, 1403/05/13

Ethics committee reference number

IR.UMSHA.REC.1403.273

Health conditions studied

1

Description of health condition studied

fatigue severity and sexual function in postmenopausal women

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Fatigue severity

Timepoint

Before the intervention, 3 and 6 weeks after the intervention

Method of measurement

Fatigue Severity Scale (FFS)

2

Description

Sexual function

Timepoint

Before the intervention, 3 and 6 weeks after the intervention

Method of measurement

Female Sexual Function Index

Secondary outcomes

1

Description

Menopausal quality of life

Timepoint

Before the intervention, 3 and 6 weeks after the intervention

Method of measurement

Menopause-Specific Quality of Life (MENQOL)

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 casei, Lactobacillus acidophilus, Lactobacillus rhamnusos,Bifidobacterium Lactis, Bifidobacterium longum, Bifidobacterium breve and with dose CFU 3×109.This drug Will be Producted by Company of Zist Takhmir.

Category

Treatment - Drugs

2

Description

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

Category

Placebo

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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Shohada.health@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

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

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R_shokouhi@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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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Person responsible for scientific 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

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Person responsible for updating data

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Hamedan University of Medical Sciences
Full name of responsible person
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Position
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
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 38381938 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