Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the Effect of Vitamin e on Depression and Anxiety in Postmenopausal Women

Protocol summary

Study aim
Investigating the effect of vitamin e on depression and anxiety in postmenopausal women

Design
Clinical trial with control group, double-blind, randomized

Settings and conduct
This study is a double-blind clinical trial (researcher and patient) that the drug and placebo are coded by a third person who does not know about the study.Postmenopausal women referred to the menopause clinic of NajafAbad (samples) are divided into two groups of odd and even using a table of random numbers, where the intervention group receives vitamin e daily for 8 weeks and the control group receives the placebo capsule containing corn oil once a day for 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: At least one year passed since the last menstruation. Menopausal Married women. Educated. Age between 45-65 years. Earn a score 10-29 from Beck Depression Questionnaire for both groups. Earn a score 8-25 from Beck Anxiety Questionnaire for both groups. Exclusion criteria: Consumption of vitamins and minerals, antidepressants and diuretics in the last 3 months. Smoking history, using drugs and alcohol during the last 3 months. History of mental or physical illness. Occurrence of an unfortunate event during the last 6 months.

Intervention groups
Intervention group: 46 Menopause women with inclusion criteria that vitamin E made by Zahravi Company of Tabriz is given 400 units daily for 8 weeks. Control group: Menopause women who have the same conditions as the intervention group, but in the control group, placebo (corn oil) made by Zahravi Company of Tabriz is used.

Main outcome variables
Depression and anxiety of postmenopausal women

General information

Reason for update
increasing the number of samples

Acronym

IRCT registration information
IRCT registration number: **IRCT20200307046719N1**
Registration date: **2020-12-04, 1399/09/14**
Registration timing: **prospective**

Last update: **2024-01-03, 1402/10/13**
Update count: **1**

Registration date
2020-12-04, 1399/09/14

Registrant information

Name
Sara Soltani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3373 8331

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Vitamin e on Depression and Anxiety in Postmenopausal Women

Public title
The Effect of Vitamin e on Depression and Anxiety in Postmenopausal Women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least one year passed since the last menstruation. Menopausal Married women. Educated. Ages between 45-65 years. Earn a score 10-29 from Beck Depression Questionnaire for both groups. Earn a score 8-25 from Beck Anxiety Questionnaire for both groups.

Exclusion criteria:
Consumption of vitamins and minerals, antidepressants and diuretics in the last 3 months. Smoking history, using drugs and alcohol during the last 3 months. History of mental or physical illness. Occurrence of an unfortunate event during the last 6 months

Age
From **45 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 92 Menopause women who are eligible for the study are divided into even and odd groups using a random number table. The samples are divided into two groups of odd and even using a table of random numbers. Each sample is given an envelope with the code (1 or 2) that the drug and placebo are coded by a third person who does not know about the study where the intervention group receives vitamin e daily for 8 weeks and the control group receives the placebo capsule containing corn oil once a day for 8 weeks (medicine and placebo are made by Tabriz Zahravi Pharmaceutical Company). If even numbers (0,2,4,6,8) are selected using a random number table, the envelope with code 1 is given to the samples and if odd numbers (1,3,5,7,9)are selected using a random number table, the envelope with code 2 is given to the samples.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, blinding and coding of drugs and placebos (vitamin e and corn oil) is done by a third person who does not know about the research. And the required number of each drug and placebo is poured separately in packages of same shape and code 1 or 2 is given. The samples and the researcher do not know the nature of the packages until the end of the research.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
No. 234, Research and Development Department, Ahvaz Jondishapur University of Medical Sciences, Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2020-02-24, 1398/12/05

Ethics committee reference number
IR.AJUMS.REC.1398.929

Health conditions studied

1

Description of health condition studied
Depressive and Anxiety Disorder

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention and eight weeks after the intervention

Method of measurement
Beck Anxiety Inventory

2

Description

Depression

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The vitamin e made by Zahravi Company of Tabriz 400 unit once daily for eight weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule containing corn oil made by Zahravi Company of Tabriz once daily for eight weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Menopausal clinic of NajafAbad-Isfahan

Full name of responsible person

Ali Tavakoli

Street address

Shahid Montazeri Hospital, Shariati Street

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NajafAbad

Province

Isfehan

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Web page address

https://hmn.mui.ac.ir/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badvi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Sara Soltani

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific

inquiries

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Associate professor

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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
Demographic information of individuals and data before and after the intervention is reported without mentioning the name

When the data will become available and for how long
Access started in 2021

To whom data/document is available
Only researchers in the field of medical universities

Under which criteria data/document could be used
It can only be used in similar research

From where data/document is obtainable
Researcher's personal email

What processes are involved for a request to access data/document
This is done by sending an email to the researcher.

Comments