Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

The effect of oral vitamin D on depression, anxiety and general health in menopausal women.

Protocol summary

Study aim
Determining the effect of vitamin D on anxiety, depression and general health in menopausal women.

Design
This is a randomized clinical trial, double-blind study with a control group and design for parallel groups. To randomization, Randomizer statistical program will be used.

Settings and conduct
Sampling will be continuously done among menopausal women who referring to the gynaecology clinic of Shahid Akbarabadi Hospital. Initially, after 15 to 20 minutes of rest in a quiet environment, each participant will complete the personal information Questionnaire, Beck Anxiety and Depression scales, General Health Questionnaire (GHQ) and Menopause Rating Scale (MRS). After completing the questionnaires, 10 ccs of venous blood will be collected to measure vitamin D, parathyroid hormone, calcium, phosphorus, AST, ALT, albumin, and creatinine. The drug registration sheet will be provided to the participants for recording regular and weekly use of vitamin D and placebo. During eight weeks of intervention, the experimental group participants will weekly receive one dose of 50,000 units vitamin D, and the control group a placebo as well. Research samples and researchers will not know the content of the package until the end of data analysis. At the end of week eight of the intervention, participants will be asked to refer to the gynaecology clinic to complete the Beck Anxiety and Depression scales, GHQ, and MRS. At this time, re-blood sampling will be done for measuring serum vitamin D, parathyroid hormone, calcium, phosphorus, AST, ALT, albumin, and creatinine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Menopausal women with 45 to 65 years old. Conditions of non-entry: Vitamin D level greater than 30 nmol/L.

Intervention groups
Vitamin D group, placebo group.

Main outcome variables
Anxiety, depression, general health.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090810002324N18**
Registration date: **2021-01-02, 1399/10/13**
Registration timing: **prospective**

Last update: **2021-01-02, 1399/10/13**
Update count: **0**

Registration date
2021-01-02, 1399/10/13

Registrant information

Name
Maryam Keshavarz

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-10, 1399/10/21

Expected recruitment end date
2021-05-31, 1400/03/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral vitamin D on depression, anxiety and general health in menopausal women.

Public title

The effect of vitamin D on depression, anxiety and general health.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 45 to 65 years. pass of at least one year since the last menstrual period. Body mass index less than 30 kg/m^2. Physical and mental health (according to personal reporting)

Exclusion criteria:

Vitamin D level above 30 nmol/L in the first blood sample. Confirmation of chronic kidney, liver, thyroid and parathyroid diseases by laboratory tests. Use of any hormone or herbal drug during the study period. Irregular consumption or missing even one dose of vitamin D or placebo.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the numbers one to one hundred twenty will be randomly divided into two groups of sixty by the Randomizer statistical program. The first and second sixty numbers will be specified by the Dana pharmaceutical company on each of the containers, containing eight soft gels oral vitamin D and eight soft gels oral placebo, respectively. Containers which marked from one to one hundred twenty will be provided to the participants in the order of entering the study. At the end of the study and before analyzing the information, all of the codes that specify the content of the containers (vitamin D or placebo) will be taken from the company, so the allocation of each participant in one of the two groups will be randomly according to the registered codes on the vitamin D and placebo containers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, researcher, and research assistant will not know how individuals allocated to each of the two intervention and control groups. All questionnaires will be gathered by the research assistant who is unaware of the allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran University of Medical sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

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Province

Tehran

Postal code

1449614535

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.IUMS.REC.1399.870

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

Depression

ICD-10 code

ICD-10 code description

3

Description of health condition studied

General health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety score
Timepoint
At the beginning of the study and before the initial sampling, then at the end of the study (8 weeks after taking the vitamin D or placebo).
Method of measurement
Beck Anxiety Inventory

2

Description
Depression score
Timepoint
At the beginning of the study and before the initial sampling, then at the end of the study (8 weeks after taking the vitamin D or placebo).
Method of measurement
Beck Depression Inventory

3

Description
General Health
Timepoint
At the beginning of the study and before the initial sampling, then at the end of the study (8 weeks after taking the vitamin D or placebo).
Method of measurement
General Health Questionnaire (GHQ)

Secondary outcomes

1

Description
Frequency and severity of menopausal symptoms
Timepoint
At the beginning of the study and before the initial sampling, then at the end of the study (8 weeks after taking the drug or placebo).
Method of measurement
The Menopause Rating Scale (MRS)

Intervention groups

1

Description
Intervention group:The participants will take weekly 50,000 units of vitamin D for a consequence of eight weeks.
Category
Prevention

2

Description
Control group: The participants will take weekly a placebo for a consequence of eight weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-abadi Hospital
Full name of responsible person
Saba Jafaripoor
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The Institute of Endocrinology and Metabolism Research and Training Center, Iran University of Medical Sciences.
Proportion provided by this source
30
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

Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Endocrinology and Metabolism Research Institute of Iran University of Medical Sciences

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Clinical & research laboratory manager

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available