

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

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1813

Email address

keshavarz@iums.ac.ir

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/m². 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

Tehran

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 Jafaripour

Street address

Mowlavi st, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۱۶۸۷۴۳۵۱۴

Phone

+98 21 5560 6034

Email

akbarabadihosp@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazeme Malakouti

Street address

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

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

vcm@iums.ac.ir

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

Phone
+98 21 8603 6062
Email
jafarzadehmehrzad@gmail.com

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
Street address
School of Nursing & Midwifery, Rashid Yasemi st.,
Valiasr St., Tehran, IRAN
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1813
Email
Keshavarz.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Endocrinology and Metabolism Research Institute of
Iran University of Medical Sciences
Full name of responsible person
Mehrzad Jafarzadeh
Position
Clinical & research laboratory manager
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
No. 10, Firooze Alley, Valiasr Square, Tehran
City
Tehran
Province
Tehran
Postal code
1593716615

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Saba Jafaripoor
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Tehran, Moulavi st
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
sabajaafaripor@gmail.com

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