

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of vitamin D supplementation effects on serum 25(OH)D3, PTH, pro-inflammatory biomarkers and neurotransmitters involved in depression, and depression status in depressive patients

Protocol summary

Study aim

Evaluation of vitamin D supplementation effects on serum 25(OH)D, PTH, pro-inflammatory biomarkers and neurotransmitters involved in depression, and depression status in depressive patients

Design

double-blind clinical trial.

Settings and conduct

In this double-blind clinical trial, patients aged 18-60y referred to Baharlou hospital with a history of mild to moderate depression diagnosed by a psychiatrist will be presented to the researcher. After receipt of a signed informed consent form, eligible patients will participate. A general demographic questionnaire will be completed by an interviewer. Individuals are randomly divided into intervention and control groups. A 10-ml venous blood sample will be collected from each participant. The case group receives 50000 IU of vitamin D every 2weeks as vitamin D supplements for 8 weeks, provided monthly. The control group receives placebo. The drug schedule of both groups will be unchanged according to the prescribing physician. After 8 weeks, blood sample will be collected from each participant and the studied indices will be evaluated. Data will be analyzed by statistical tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having mild to moderate depression age:18 to 60 y non-inclusion criteria: a history of heart infarction a history of angina a history of stroke a history of kidney stones a history of high blood pressure (systolic blood pressure higher than 174 or diastolic blood pressure higher than 104 mm Hg) a history of liver disease a history of hyperparathyroidism pregnancy and/or lactation Reproductive-aged women (under 50 years old) who are not receiving adequate contraception consuming nutritional supplement containing vitamin D from 2 months ago

Intervention groups

Case: Patients who receive vitamin D supplementation.

Control: Patients receiving placebo.

Main outcome variables

serum 25(OH)D concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170926036425N1**

Registration date: **2018-09-17, 1397/06/26**

Registration timing: **retrospective**

Last update: **2018-09-17, 1397/06/26**

Update count: **0**

Registration date

2018-09-17, 1397/06/26

Registrant information

Name

Mina Kaviani

Name of organization / entity

National Nutrition and Food Technology Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0658

Email address

m_kaviani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D supplementation effects on serum 25(OH)D3, PTH, pro-inflammatory biomarkers and neurotransmitters involved in depression, and depression status in depressive patients

Public title

Vitamin D and depression

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

having mild to moderate depression age: 18 to 60 y

Exclusion criteria:

having a history of heart infarction having a history of angina having a history of stroke having a history of kidney stones having a history of high blood pressure (systolic blood pressure higher than 174 or diastolic blood pressure higher than 104 mm Hg) having a history of liver disease having a history of hyperparathyroidism pregnancy and/or lactation Reproductive-aged women (under 50 years old) who are not receiving adequate contraception consuming nutritional supplement containing vitamin D from 2 months ago

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method is used. Each person is given a random code when entering the study, and each person enters one of the two groups, depending on the received code.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants, clinical caregivers, researcher, outcome evaluator, data analyst, and data monitoring safety committee are kept blind and they are completely

unaware of how to place specimens in the case or control group and of the consumption of supplement or placebo. Placebos used, apparently, will be quite similar to supplements.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Nutrition and food Technology Research institute, Shahid Beheshti University of Medical Sci

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No. 7, Shahid Hafezi (West Arghavan) Ave., Farahzadi Blvd., Qods (Gharb) Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.SBMU.nnftri.Rec.1396.185

Health conditions studied**1****Description of health condition studied**

depression

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

Primary outcomes**1****Description**

serum 25(OH)D concentration

Timepoint

baseline and 8 weeks after intervention

Method of measurement

measurement of serum level of 25OHD

Secondary outcomes

1

Description

proinflammatory biomarkers

Timepoint

baseline and 8 weeks after intervention

Method of measurement

measurement of serum hs-CRP, IL-6, IL-1 β concentrations

2

Description

bone biomarker

Timepoint

baseline and 8 weeks after intervention

Method of measurement

measurement of serum parathormone concentration

3

Description

some neurotransmitters involved in depression

Timepoint

baseline and 8 weeks after intervention

Method of measurement

measurement of serum oxytocin and platelet serotonin concentrations

4

Description

depression status

Timepoint

baseline and 8 weeks after intervention

Method of measurement

Using Beck questioner

Intervention groups

1

Description

Intervention group: Every two weeks receives 50000 IU vitamin D as vitamin D supplementation for 8 weeks, which is provided on a monthly basis.

Category

Treatment - Other

2

Description

Control group: Every two weeks receives a placebo apparently quite similar to vitamin D supplement, for 8 weeks, which is provided on a monthly basis.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharloo hospital

Full name of responsible person

Dr Mohammad Arefi

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Behdari St.- Rah ahan Sq.-Tehran-Iran

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<http://baharloohospital.tums.ac.ir/baharloo/%D8%AA%D8%A7%D8%B1%DB%8C%D8%AE%DA%86%D9%87-%D8%A8%DB%8C%D9%85%D8%A7%D8%B1%D8%B3%D8%AA%D8%A7%D9%86-%D8%A8%D9%87%D8%A7%D8%B1%D9%84%D9%88/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr Esmat Nasseri

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Web page address

<http://nnftri.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition and Food Technology Research Institute

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**

Islamic Azad University

Full name of responsible person

Mina Kaviani

Position

PhD student in Biochemistry

Latest degree

Master

Other areas of specialty/work

Biochemistry, Nutrition

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**National Nutrition and food Technology Research
institute, Shahid Beheshti University of Medical Sci**Full name of responsible person**

Dr Tirang Reza Neyestani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition; Immunology; Biochemistry

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Ph.D. student in biochemistry

Latest degree

Master

Other areas of specialty/work

Biochemistry, Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPDIn order to comply with medical ethics, the findings of
this study will only be reported in groups.**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 CodeUndecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**

Yes - There is a plan to make this available

Title and more details about the data/documentThe findings from this study will only be reported in
groups and the information of the participants in the
study will remain confidential.**When the data will become available and for how long**

Data will available after publishing the result of project

To whom data/document is availableData will available for people working in academic
institutions

Under which criteria data/document could be used

It will be determined at request time

From where data/document is obtainable

Getting the results of this research in the form of scholarly articles is possible through referencing and searching on valid websites.

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

The findings from this research will be available in scientific articles published.

Comments