

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of vitamin D supplementation on insulin resistance and inflammatory factor in patients with depression

Protocol summary

Study aim

The aim of this study is to determine the effect of vitamin D supplementation on severity depression and metabolic status among patients with major depressive disorder.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 40 patients with major depressive disorder of eligible and referred to Kargarnejad Hospital to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with major depressive according to DSM-IV-TR criteria, aged 18 to 65 years, the least score 15 on Hamilton Depression scoring system. Exclusion criteria: History of coronary infarction, angina pectoris, stroke or renal stone disease Pregnant or lactating women Smokers Liver problems Substance abuse Non-normal creatinine concentrations Taking dietary supplements during the last 2 months.

Intervention groups

Intervention: Patients will be assigned to receive either the vitamin D supplements (intervention group: n=20) or placebo (control group: n=20).

Main outcome variables

Depression (primary outcome) and metabolic profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201412065623N29**

Registration date: **2014-12-19, 1393/09/28**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

Registration date

2014-12-19, 1393/09/28

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2014-11-04, 1393/08/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D supplementation on insulin resistance and inflammatory factor in patients with depression

Public title

Effect of supplementation in treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with major depressive according to DSM-IV-TR criteria Aged 18 to 65 years The least score 15 on Hamilton Depression scoring system.

Exclusion criteria:

History of coronary infarction, angina pectoris, stroke or renal stone disease Pregnant or lactating women Smokers Liver problems Substance abuse Non-normal creatinine concentrations Taking dietary supplements during the last 2 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either vitamin D supplements (n=20) or placebo (n=20). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo has been used to achieve masking of participants and investigators. The researchers and patients will be concealed until the final analyses by a trained staff.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2014-11-01, 1393/08/10

Ethics committee reference number

4230/1/5/29/p

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Depression

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Fasting plasma glucose

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic

2

Description

Triglycerides

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic

3

Description

Total antioxidant capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

5

Description

Cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic

6

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

Intervention groups

1

Description

Intervention group: Vitamin D pearl, 50000 IU, weekly, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo pearl, weekly, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Kargarnejad Hospital

Full name of responsible person

Zahra Sepehrmanesh

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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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