Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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

Isfehan

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
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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
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Position
PhD of Nutrition
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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