Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The Effect of Vitamin D Supplementation on Metabolic Syndrome Indicators among Food In-secured, Vitamin D Deficient ; A Randomised Clinical Trial

Protocol summary

Summary

General objective: To assess the effect of vitamin D supplementation on metabolic syndrome among older adults in Karaj city, Alborz province in Iran. A two-arm randomised controlled trial (RCT) will be conducted by recruiting participants. Inclusion Criteria: Food insecure, metabolic syndrome; Vitamin D deficiency Exclusion Criteria: those who are already taking any type of vitamin D supplements, Individuals with a history of allergy, Those subjects with serious medical condition such as cancer, heart attack, stroke, and etc., Intervention group: The intervention will start from 21 of April 2017 to 22 of June 2017 for 2 months. The intervention group will receive 50,000 U vitamin D3 per week (equivalent to 1,250 µg) for 8 weeks plus pamphlets and brochures about nutrition and health at the beginning of the study. Control group: The respondents in control group will receive placebo plus brochures and pamphlets related to nutrition and health at the beginning of the study. The data collection process will identify the older adults for both groups; intervention and control. Consent will be obtained from those who are eligible. Anthropometric measurement (height, weight, body mass index, and waist circumference), blood pressure measurement, blood taking and three-day food record will be obtained during baseline from all study respondents in the intervention and control groups. Primary Output: Achieving 25 (OH) D upper than insufficient serum 25(OH) D level >30 ng/l. Secondary Output: Reduction anthropometry (body mass index (BMI) and waist circumference (WC), Improved Biomarkers indicators (lipid profile, fasting blood fast), improved blood pressure before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121831449N1**
Registration date: **2017-05-08, 1396/02/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-08, 1396/02/18

Registrant information

Name
Maryam Zarei
Name of organization / entity
Ministry of Health and Medical Education
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Ministry of Health, Nutrition Department.

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vitamin D Supplementation on Metabolic Syndrome Indicators among Food In-secured, Vitamin D Deficient ; A Randomised Clinical Trial

Public title
Effect of vitamin D supplementation on metabolic syndrome in elderlies
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Food insecure, waist Circumference>90 cm, body mass index ≥30 kg/m2, fasting blood sugar>100 mg/dl, high blood pressure (systolic >135 mmHg and diastolic >85 mmHg) and dyslipidaemia (Low density lipoprotein≥ 240 mg/dl, high density lipoprotein<40 mg/dl, total cholesterol≥ 160 mg/dl, triglyceride ≥ 200 mg/dl), serum 25(OH) D level <30 ng/ml, no use of vitamin D supplementation before 60 days. Exclusion criteria: An inability or unwillingness to participate, those who are already taking any type of vitamin D supplements, Individuals with a history of allergy, those subjects with serious medical condition such as cancer, heart attack, stroke, and etc., illness that required corticosteroids or insulin, drugs are known to influence vitamin D level, steroids, anti-acids, oestrogen, people with conditions that contradict vitamin D supplementation, for example, a history of hypocalcaemia, hepatic disease or renal stones, sarcoidosis, or malignancy.
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Simple allocation randomisation will be accomplished with no stratification using a restricted (10 blocks) random number to ensure equivalence of numbers in each group using www.graphpad.com/quickcalcs/randomn2.cfm. Simple allocation randomization will be accomplished with no stratification using a restricted (10 blocks) random number to ensure equivalence of numbers in each group using www.graphpad.com/quickcalcs/randomn2.cfm. From 120 respondents (60 respondents for each group), the odd numbers will be allocated to group intervention and the even numbers to group control. In every 10 number blocks from the random table, the sequence will be checked to ensure the even numbers are equal to the odd numbers. Each number in the random table will be given a study number and assigned into one of the study groups. A table for the allocation of the participants in the study will be composed and kept in a sealed envelope. Numbered, identical, opaque sealed envelopes will be used for respondents' allocation. The allocation envelope contains the treatment allocation identification showing either group 1 or group 2.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research deputy Alborz Medical university
Street address
Taleghani Boulevard
City
Karaj
Postal code
Approval date
2017-02-13, 1395/11/25
Ethics committee reference number
ABZUMS.REC.1395.114

Health conditions studied

1

Description of health condition studied
Metabolic syndrome (diabetes, obesity, blood pressure and hyperlipidemia)
ICD-10 code
E10, E11,
ICD-10 code description
Metabolic disorders and nutritional

Primary outcomes

1

Description
25(OH)D
Timepoint
8 weeks
Method of measurement
blood taking (before intervention and after intervention, 2 months later)

Secondary outcomes

1

Description

Fasting Blood Pressure (FBS)

Timepoint

8 weeks

Method of measurement

blood taking before and after intervention (2months)

2

Description

Antropometrics indicators

Timepoint

8 weeks

Method of measurement

measuring height and weight before and after intervention (2months)

3

Description

Blood Pressure

Timepoint

8 weeks

Method of measurement

measure before and after intervention (2months)

4

Description

Hyperlipidemia

Timepoint

8 weeks

Method of measurement

blood taking before and after intervention (2months)

Intervention groups

1

Description

Intervention group: The respondents in intervention group will receive 50000 vitamin D for 8 weeks. Plus, brochures and pamphlets related to nutrition and health.

Category

Treatment - Drugs

2

Description

Control group: The respondents in control group will receive placebo per week for 8 weeks. Plus brochures and pamphlets related to nutrition and health at the beginning of the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Karaj health centres, Alborz Medical university

Full name of responsible person

DR. Mostafa Qorbani

Street address

Taleghani Boulevard

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ministry of Health, Nutrition Deprtment

Full name of responsible person

Zahra Abdollahi

Street address

Block A, Floor 10, East Ivanak, Farahzadi Boulevard, Sanat Square.,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ministry of Health, Nutrition Deprtment

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Alborz Medical university

Full name of responsible person

Mostafa Qorbani

Position

PhD,Assistant Professor

Other areas of specialty/work

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Fax

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ministry of Health and Medical Education , Nutrition Department

Full name of responsible person
Maryam Zarei

Position
Master of nutrition, Phd student

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Nutrition Officer,Nutrition Department, Ministry of Health and Medical Education

Full name of responsible person
Maryam Zarei

Position
PhD candidate

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty