Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of vitamin D3 supplementation on anxiety, depression, sleep quality, physical morbidity and oxidative stress in university students

Protocol summary

Summary

The aim of this placebo controlled double blind randomized clinical trial will be to assess the effect of vitamin D3 supplementation on anxiety, depression, sleep quality, physical morbidity and oxidative stress in university students. Inclusion criterion is students ranged in age from 20 to 25 years old. The main exclusion criterion is concurrent other vitamin D supplements use during the study. A total of 50 students will be recruited from Kerman University of Medical Sciences. These students will be divided in to two groups (intervention and placebo), each have 25 patients, using block randomization. After signing informed consent form by students, vitamin D3 will be administered 100000 units at baseline and after one month in interventional group and students will take placebo with the same dose and frequency in control group. Depression, anxiety, sleep quality and physical morbidity will be evaluated using self-reported questionnaires at baseline and after 2 months. The level of 25-hydroxyvitamin D and oxidative stress biomarkers is measured at baseline and after 2 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703076026N5**
Registration date: **2017-03-10, 1395/12/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-10, 1395/12/20

Registrant information

Name

Fatemeh Dabaghzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5034

Email address

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2018-05-01, 1397/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitamin D3 supplementation on anxiety, depression, sleep quality, physical morbidity and oxidative stress in university students

Public title

Evaluating the effect of vitamin D3 supplementation on anxiety, depression, sleep quality, physical morbidity and oxidative stress in university students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: University student in the 20-25 age range; Having an underlying disease, Exclusion:

Concurrent other vitamin D supplements use during the study period

Age
From **20 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of Medical Sciences

Street address
Tahmasb abad Ave

City
Kerman

Postal code

Approval date
2017-01-23, 1395/11/04

Ethics committee reference number
IR.KMU.REC.1395.551

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
Depression

ICD-10 code
F32.9

ICD-10 code description
Depressive episode, unspecified

3

Description of health condition studied
Sleep disorder

ICD-10 code
G47

ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Mental disorder

Timepoint
At baseline and after 2 months

Method of measurement
Questionnaires

2

Description
Oxidative stress

Timepoint
At baseline and after 2 months

Method of measurement
Oxidative stress biomarkers

Secondary outcomes

1

Description
Physical morbidity

Timepoint
At baseline and after 2 months

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention: Two vitamin D3 pearls (50000 IU) at baseline and after 1 month

Category
Treatment - Drugs

2

Description
Control: Two placebo Pearls at baseline and after on month

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Dabaghzadeh
Street address
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman Univesity of Medical Sciences
Full name of responsible person
Miz. Hasani
Street address
Tahmasb abad Ave
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman Univesity of Medical Sciences
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
Kerman University of Medical Sciences
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Fatemeh Dabaghzadeh
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Person responsible for updating data

Contact
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Other areas of specialty/work
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00
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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