

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

dabaghzadeh@razi.tums.ac.ir

##### 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 University 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 University 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  
**Full name of responsible person**  
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Clinical Pharmacist  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Fax**  
**Email**  
**Web page address**

## 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*