

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of vitamin D on depression in the elderly population in Kashan, Iran in 2016

#### Protocol summary

##### Summary

The main purpose of consumption of vitamin D are associated with depression in the elderly. Characteristics of the study population: the elderly over 60 years of Kashan in 2016. Inclusion criteria: Iranian citizenship; age over 60 years old; the ability to speak Farsi and answer questions; lack of mental retardation, not using vitamin D; no disability; no history of mental illness other than depression. Exclusion criteria: uncooperative and refused to continue treating patients in the intervention group and vitamin D; vitamin D use in the control group; the occurrence of any severe stress, such as hospitalization or death of relatives in both groups during the study. In this study, 30 patients in each group will be evaluated intervention and non-intervention. The treatment of depression in patients under medical supervision with GDS questionnaire will be examined. The patients who receive the questionnaire in the study are the top 5 score. Each serum 25-hydroxyvitamin D level of 5 ml of venous blood clots research and will be sent to the laboratory in Kashan BC. People who are deficient in vitamin D, including sex, randomly divided into two intervention and control groups. Patients in the intervention group for 8 weeks of 50,000 IU vitamin capsule, one capsule per week will be prescribed. In the control group taking a placebo with the same statement prepared by the pharmaceutical company producing the drug is used. Routine treatment of your patients as directed by their doctor. After 8 weeks GDS questionnaire and serum levels of vitamin D will be investigated. The ethical principles of patients and the control group after 8 week study of vitamin D will be treated. 2. In the second stage to determine. Natural rate ranging between 100-30 ng / mL, less than 30 ng / mL is considered as deficiency . The testing by ELISA is carried out in the laboratory of Milad Hospital, Tehran, Iran.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042527587N1**  
Registration date: **2016-07-04, 1395/04/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-04, 1395/04/14

##### Registrant information

##### Name

saeid Khademolhosseini

##### Name of organization / entity

School of Nursing and Midwifery, Kashan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5556 0063

##### Email address

khadem-sa@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2016-03-01, 1394/12/11

##### Expected recruitment end date

2017-03-02, 1395/12/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of vitamin D on depression in the elderly population in Kashan, Iran in 2016

**Public title**

The effect of vitamin D on depression in the elderly

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1. Iranian citizenship; 2. Age older than 60 years old; 3. The ability to speak in Farsi, and answering questions; 4. Lack of mental retardation; 5. Not using vitamin D; 6. No disability ;7. No history of mental illness other than depression. Exclusion criteria: 1. Uncooperative and refused further treatment and vitamin D patients in the intervention group; 2. Vitamin D administration in control group; 3. The occurrence of any severe stress, such as hospitalization or death of relatives in both groups during the study.

**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: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****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**

Kashan University of Medical Sciences, 5th km Ghotb Ravandi blvd.

**City**

Kashan

**Postal code**

8715985191

**Approval date**

2016-03-08, 1394/12/18

**Ethics committee reference number**

IR.KUM\$.RIC.1394.133

**Health conditions studied****1****Description of health condition studied**

Depression

**ICD-10 code**

F00-F98

**ICD-10 code description**

Mental and behavioral disorders

**Primary outcomes****1****Description**

Depression

**Timepoint**

Before and two months after intervention

**Method of measurement**

Geriatric Depression Scale

**Secondary outcomes****1****Description**

vitamin D in blood

**Timepoint**

before intervention and 2 months after

**Method of measurement**

blood test

**Intervention groups****1****Description**

Patients in the intervention group for 8 weeks of 50,000 IU vitamin capsules will be administered one capsule per week.

**Category**

Treatment - Drugs

**2****Description**

In the control group taking a placebo with the same statement prepared by the pharmaceutical company producing the drug is used.

**Category**

Placebo

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Kargrnzhad hospital in Kashan  
**Full name of responsible person**  
Doctor Negin Masoudi Alavi  
**Street address**  
5th km Ghotb Ravandi blvd.  
**City**  
Kashan

**Fax**  
+98 31 5554 6633  
**Email**  
masudialavi\_N@kaums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kashan University of Medical Sciences & Research  
Department  
**Full name of responsible person**  
Gholam Ali Hamidi  
**Street address**  
5th km Ghotb Ravandi blvd.. doctor-Vice Chancellor  
for Research and Technology  
**City**  
Kashan

#### 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 & Research  
Department

#### 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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Dr. Negin Masoudi Alavi  
**Position**  
Nursing Ph.D.  
**Other areas of specialty/work**  
**Street address**  
Kashan University of Medical Sciences, 5th km Ghotb  
Ravandi blvd.  
**City**  
Kashan  
**Postal code**  
8715985191  
**Phone**  
+98 31 5554 6633

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
School of Nursing and Midwifery, Kashan  
**Full name of responsible person**  
Dr. Negin Masoudi Alavi  
**Position**  
Nursing Ph.D.  
**Other areas of specialty/work**  
**Street address**  
Kashan University of Medical Sciences, 5th km Ghotb  
Ravandi blvd.  
**City**  
Kashan  
**Postal code**  
8715985191  
**Phone**  
+98 31 5554 6633  
**Fax**  
+98 31 5554 6633  
**Email**  
masudialavi\_N@kaums.ac.ir  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Dr. Negin Masoudi Alavi  
**Position**  
Nursing PhD / Professor  
**Other areas of specialty/work**  
**Street address**  
Kashan University of Medical Sciences, 5th km Ghotb  
Ravandi blvd.  
**City**  
Kashan  
**Postal code**  
8715985191  
**Phone**  
+98 31 5554 6633  
**Fax**  
+98 31 5554 6633  
**Email**  
masudialavi\_N@kaums.ac.ir  
**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*