Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

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
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Nursing Ph.D.
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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