

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamin D supplement on the score and quality of sleep in 20 to 50 year-old people with sleep disorders compared with control group

Protocol summary

Summary

Objective of study: Assessing the effect of vitamin D supplement on the score and quality of sleep in 20 to 50 year-old people with sleep disorders. Design of the study: This is a randomized, double-blinded, placebo-intervention trial. Conduct: This study will be conducted in Golestan Hospital, Ahwaz. The eligible subjects will be chosen by convenience sampling and randomly will be categorized into two intervention and control groups, each including 45 people. Subjects: Ninety people, all from 20 to 50 years old and with sleep disorder, who score 5 or higher based on Pittsburgh Sleep Quality Index. Intervention: After completing basic information and filling in Pittsburgh sleep quality questionnaire, intervention group will receive vitamin D tablets (50000 units), one tablet every fortnight, for 2 months; meanwhile, control group will receive Placebo. Inclusion criteria: Personal willingness to participation; Aging 20 to 50 year old; Suffering sleep disorder based on Pittsburgh Sleep Quality Index; No allergy to vitamin D supplement; No mental psychic disorder; No consumption of sleep medication or anti-depression; No consumption of vitamin D supplement three months before intervention. Exclusion criteria: Allergy to vitamin D supplement; Consumption of sedative drugs; Suffering mental problems such as hyper-depression or excessive anxiety; Pregnancy or lactation; Drinking or smoking; Lack of willingness to participation. Main outcome variables: Subjects' sleep quality will be evaluated by Pittsburgh sleep quality questionnaire before intervention and 2 months after it. Secondary outcome variables: Serum vitamin D level will be evaluated before intervention and 2 months after it.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122725723N1**

Registration date: **2016-02-14, 1394/11/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-14, 1394/11/25

Registrant information

Name

MOHAMMAD ABOLFATHI

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 1984

Email address

abolfathi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-02-06, 1394/11/17

Expected recruitment end date

2016-05-06, 1395/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplement on the score and quality of sleep in 20 to 50 year-old people with sleep disorders compared with control group

Public title

The effect of vitamin D supplement on the score and quality of sleep in 20 to 50 year-old people with sleep disorders compared with control group

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Personal willingness to participation; Aging 20 to 50 year old; Suffering sleep disorder based on Pittsburgh Sleep Quality Index; No allergy to vitamin D supplement; No mental psychic disorder; No consumption of sleep medication or anti-depression; No consumption of vitamin D supplement three months before intervention. Exclusion criteria: Allergy to vitamin D supplement; Consumption of sedative drugs; Suffering mental problems such as hyper-depression or excessive anxiety; Pregnancy or lactation; Drinking or smoking; Lack of willingness to participation.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Hwy, Ahvaz, Khuzestan

City

Ahvaz

Postal code

61357-15794

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.AGUMF.REC.1394.514

Health conditions studied

1

Description of health condition studied

Sleep disorders

ICD-10 code

F51.8

ICD-10 code description

Other nonorganic sleep disorders

Primary outcomes

1

Description

Sleep quality

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

25 Hydroxy Vitamin D3 Serum

Timepoint

Before intervention and 2 months after intervention

Method of measurement

ELISA

Intervention groups

1

Description

The control group will receive one Placebo tablet every fortnight for 2 months. These tablets contain edible paraffin oil.

Category

Placebo

2

Description

The intervention group Will receive 50000 units of vitamin D tablets, one tablet every fortnight for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Abolfathi Mohammad
Street address
Golestan Hwy, Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences
Full name of responsible person
Saky Nader
Street address
Golestan Hwy, Ahvaz
City
Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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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