

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin D supplement consumption on muscle strength, muscle function and body composition in middle-aged women

Protocol summary

2014-12-22, 1393/10/01

Summary

Sarcopenia, the loss of muscle mass and strength with aging, is a common cause of functional limitations, disability and mortality in older age which is reversible and preventable. Previous cross-sectional and prospective studies suggested vitamin D deficiency is common in elderly people and is associated with muscle weakness, weight gain, and increased risk of sarcopenia in older adults. However, effect of vitamin D supplement on body composition, muscle strength and muscle function is not clear. Therefore, we have designed a double blind, Placebo-controlled, randomized clinical trial to investigate the effect of vitamin D supplement consumption on muscle strength, muscle function and body composition in middle aged women. 74 women, aged 40-50 years old, who are eligible for this study will be recruited from Iran medical university. Informed consent form will be completed by each participant at the beginning of study. Participants will be divided in two groups randomly, receiving either 1000 IU vitamin D tablet or placebo for 12 weeks. Muscle strength and function markers (handgrip strength, knee extension strength, time get up and go) and body composition will be determined at baseline and the end of the study. Key words: sarcopenia, muscle strength, muscle function, body composition, vitamin D

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Iran University of Medical Sciences

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-01-05, 1393/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplement consumption on muscle strength, muscle function and body composition in middle-aged women

Public title

Effect of vitamin D supplement consumption on muscle strength, muscle function and body composition in middle-aged women

Purpose

Prevention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112182365N6**

Registration date: **2014-12-22, 1393/10/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Inclusion/Exclusion criteria

Inclusion criteria: Healthy, aged 40-55 years old women; Premenopausal; BMI 18.5-29.9 kg/m²; 25(OH)-D<25 nmol/l; Not ovariectomized; Women must be without following diseases: uncontrolled hypertension; diabetes; cardiovascular diseases; renal disorders; asthma; liver diseases; thyroid or parathyroid diseases; bone disorders; gastrointestinal diseases; infectious diseases and hyperphosphatemia; Not taking W3 fatty acids or fish oil; hormonal products, any supplements including vitamins and minerals; Not using one of the following medications: anti-inflammatory drugs (including NSAIDs and steroids); phenobarbital, phenytoin; anti-acid drugs, diuretics and laxative drugs; Not using any drug and supplement that have an effect on weight status; Voluntary participation. Exclusion criteria: Acute disease; Migration; Any event that has an effect on health status

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **74**

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

School of Health, Iran University of Medical Sciences

Street address

Tehran, Hemat Express way, Iran University of Medical Sciences, School of Health

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

24988-93/9/8

2

Ethics committee

Name of ethics committee

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Street address

Tehran, Hemat Express way, Iran University of Medical Sciences, School of Public Health

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

24988-93/8/4

Health conditions studied

1

Description of health condition studied

Sarcopenia, Muscle weakness, Decrease of muscle strength

ICD-10 code

M62.5

ICD-10 code description

Muscle wasting and atrophy, not elsewhere classified

Primary outcomes

1

Description

Improvement of muscle strength in hand and foot, Improvement of body composition

Timepoint

12 weeks

Method of measurement

Dynamometer, Handgrip, BIA

Secondary outcomes

1

Description

Increase of serum 25(OH)-D

Timepoint

12 weeks

Method of measurement

Laboratory Kit

Intervention groups

1

Description

Vitamin D supplement in a DRI dose

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Vafa

Street address

Hemat Expressway, Iran University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Ali Javadmoosavi

Street address

Hemat Express way, Iran University of Medical Sciences

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Position

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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