Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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

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

2014-12-22, 1393/10/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chanceller 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

Inclusion/Exclusion criteria
Inclusion criteria: Healthy، aged 40-55 years old women; Premenopaused; BMI 18.5-29.9 kg/m2; 25(OH)-D<25 nmol/l; Not ovariectomized; Women must be with out 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 have effect on weight status; Voluntary participitation. Exclusion criteria: Acute disease; Migration; Any event that 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
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Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
24988-93/9/8

2

Ethics committee
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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
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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

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Person responsible for updating data

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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