

Effect of single high-dose or daily low-dose vitamin D on muscle strength in older women

Submission date 24/06/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/07/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Vitamin D deficiency is a public health problem. There are many consequences of vitamin D deficiency. Many studies have investigated the effects of vitamin D supplementation on muscle strength, but the results remain controversial. There is also contradictory data about which administration route is healthier. We aimed to compare the effects and safety of single high-dose with daily low-dose oral colecalciferol on 25(OH)D levels and muscle strength in postmenopausal women with vitamin D deficiency or insufficiency.

Background and study aims

Vitamin D is involved in calcium absorption, immune function and protecting bone, muscle and heart health. Vitamin D deficiency is a common health problem. Vitamin D supplements are used to improve vitamin D status; however, there is contradictory information on what doses to give and how often they should be given. Many studies have investigated the effects of vitamin D supplementation on muscle strength, but the results remain controversial. We aimed to compare the effects and safety of a single high dose with daily low doses of oral colecalciferol (vitamin D3) on vitamin D levels and muscle strength in postmenopausal women with vitamin D deficiency or insufficiency.

Who can participate?

Postmenopausal women who had low vitamin D levels in their blood

What does the study involve?

One group received a low dose of vitamin D3 once a day by mouth and the second group received a single high dose of vitamin D3 by mouth. Blood vitamin D levels and muscle strengths were measured at before the women took the vitamin D3 and at the 4th and 12th weeks.

What are the possible benefits and risks of participating?

Participants will receive treatment for their vitamin D deficiency. Side effects from vitamin D supplements are not common and occur almost exclusively in people who take long-term, high-dose supplements without monitoring blood levels. Elevated calcium levels, nausea, vomiting, poor appetite, stomach pain, constipation or diarrhea, kidney injury are potential side effects of excessive vitamin D intake.

Where is the study run from?

The Endocrinology and Metabolism Clinic of Ankara Diskapi Training and Research Hospital

When is the study starting and how long is it expected to run for?

November 2014 to February 2016

Who is funding the study?

There is no funding source for the study. The study coordinators will cover all expenses and participants will not be responsible for any expenses.

Who is the main contact?

Dr Mahmut Apaydin, drmahmutapaydin@gmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Mahmut Apaydin

Contact details

Diskapi Training and Research Hospital

Ankara

Türkiye

06110

0905052349090

drmahmutapaydin@gmail.com

Additional identifiers

Protocol serial number

19/36

Study information

Scientific Title

The effects of single high-dose or daily low-dosage oral colecalciferol treatment on vitamin D levels and muscle strength in postmenopausal women

Study objectives

Many studies have investigated the effects of vitamin D supplementation on muscle strength, but the results remain controversial. We aimed to compare the effects and safety of single high-dose with daily low-dose oral colecalciferol on 25(OH)D levels and muscle strength in postmenopausal women with vitamin D deficiency or insufficiency

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study design

Non-randomised parallel-arm study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Effect on muscle strength of vitamin D supplementation

Interventions

60 healthy postmenopausal women who had serum vitamin D levels <20 ng/ml (50 nmol/l) were enrolled in the study. Group 1 (n=32) was given daily oral dosages of 800 IU vitamin D3, and group 2 (n=28) was given a single oral dose of 300,000 IU vitamin D3. Serum vitamin D levels and muscle strengths were measured at baseline, week 4 and week 12.

Intervention Type

Supplement

Primary outcome(s)

25OH vitamin D levels 3 months after treatment

Key secondary outcome(s)

Muscle strength 3 months after treatment. Muscle strength tests were performed at 60° using a Biodex system 3 isokinetic dynamometer.

Completion date

01/02/2016

Eligibility

Key inclusion criteria

1. Healthy
2. Postmenopausal
3. Aged 50-68 years
4. Vitamin D level <20 ng/ml (50 nmol/l)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Individuals who had granulomatous conditions, thyroid disease, malabsorption syndromes, liver disease, kidney disease, diabetes or postural instability (cerebellar disease, vestibular disease, vitamin B12 deficiency, drugs)
2. Individuals taking anticonvulsants, calcium or vitamin D supplements, barbiturates, or steroids in any form

Date of first enrolment

15/02/2015

Date of final enrolment

15/10/2015

Locations**Countries of recruitment**

Türkiye

Study participating centre**Diskapi Training and Research Hospital**

İrfan Bastug Cad. 06110, Altındag/ Ankara, Turkey

Ankara

Türkiye

06110

Sponsor information**Organisation**

Diskapi Training and Research Hospital

ROR

<https://ror.org/04bghze60>

Funder(s)**Funder type**

Not defined

Funder Name

None

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Mahmut Apaydin.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/07/2018		Yes	No