ISRCTN14226530 https://doi.org/10.1186/ISRCTN14226530

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

Registration date
04/07/2018

Overall study status
Completed

Last Edited
23/07/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
Medical Ethics Committee of Ankara Diskapi Training and Research Hospital, 26/01/2015, ref: 19/36

Study design
Non-randomised parallel-arm study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
25OH vitamin D levels 3 months after treatment

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

Overall study start date
01/11/2014

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

Age group
Adult

Sex
Female

Target number of participants
60

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

Sponsor details
-
Ankara
Türkiye
06110
0903125962000
info@diskapieah.gov.tr

Sponsor type
Hospital/treatment centre

Website
http://www.diskapieah.gov.tr/diskapi1/

ROR
https://ror.org/04bghze60

Funder(s)

Funder type
Not defined

Funder Name
None

Results and Publications

Publication and dissemination plan
We are planning to publish it in BMC Endocrine Disorders

Intention to publish date
01/12/2018

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