What is the effect of 2 different treatment strategies of Vitamin D supplementation on 25(OH)D3 serum concentration? And what are the benefits for older people? A prospective observational clinical study.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40026

Source
ToetsingOnline

Brief title
EVITA-D

Condition

- Other condition
- Vitamin related disorders

Synonym
25 (OH)D3 deficiency, colecalciferol, Vitamin D deficiency

Health condition

functionele stoornissen/mobiliteit

Research involving
Human

Sponsors and support

Primary sponsor: Tergooi locatie Blaricum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 25(OH)D, functional assessment, suppletion, vitamin D

Outcome measures

Primary outcome

25(OH)D3 levels after 12 months of supplementation

Secondary outcome

Functional mobility (measurements: gait speed, timed get up and go test,

timed-stands test), fall- and fracture frequency , 25(OH)D3 levels after

loading dose regimen and after 6 months of supplementation.

Study description

Background summary

In older people, a vitamin D deficiency is common. Vitamin D deficiency is associated with osteoporosis, osteomalacia and is related to an increased fracture risk, because of a decreased bone mineral density and muscle mass and an increased risk of falling. In addition, a deficiency of vitamin D is possibly associated with conditions and diseases, beyond bone and musculoskeletal health. Worldwide and within the Netherlands, there is still no consensus concerning the optimal dosage of vitamin D supplementation to optimize reduction of the named health risks. Recent research suggests that a higher dose of supplementation and reaching a higher serum concentration of vitamin D (25(OH)D3) is necessary to further decrease the fall and fracture

risk. Our hypothesis is, that a higher maintenance dose of vitamin D induces a higher steady state blood level, and therefore would increase muscle strength and functional mobility, which would reduce the risk of falling and fractures.

Study objective

Primary objective of the study is to determine the effect of 2 different treatment strategies of vitamin D supplementation on 25(OH)D3 serum concentration after 12 months of supplementation. Secondary objectives are to determine the effects on the functional mobility and fall and fracture frequency. Also the 25(OH)D3 serum concentration will be measured after loading dosage regimen and after 6 months of supplementation.

Study design

A prospective, observational clinical study

Study burden and risks

The study has negligible risks and minimal impact for participating patients. Patients need to visit the outpatient clinic 2 more times, at 6 and 12 months after their initial referral. Within these 2 visits, they will undergo mobility performance measurements (TGUG, timed-stands test, gait speed) and blood sampling (25(OH)D3, (corrected) calcium, albuminia en creatinine/MDRD). An extra blood sample will be collected at 7 weeks after start of supplementation. At baseline and after 12 months, patients will be asked to fill out an inventory of falling and fractures in the past year. Also, the patients will be asked to note down (scoring list) every fall with the date, the circumstances and if the fall led to bone fractures.
Patients with a vitamin D deficiency who will not participate in this study, will receive supplementation of vitamin D according to the local protocol of the clinic.
There are no health related risks with these dosages of vitamin D supplementation. Maintenance doses up to 4000 IE a day are reported to be safe. If possible, the visits and tests of the study will be incorporated within the regular visits to the Geriatrician. There is a need to extend our knowledge about vitamin D supplementation in elderly, because of the serious consequences of vitamin D deficiency , and uncertainty about the optimal dosage of vitamin D supplementation in older patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Geriatric outpatients aged 65 years and older
- 25 (OH)D3 concentration < 50 mmol/L

Exclusion criteria

hypercalcemia (*50.4 mg/dl), severe renal insufficiency (MDRD < 30 ml/min), liver failure, Kidney stones/calculi, hyperthyroidism and hypothyreoidism, terminal illness, no informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL42540.018.14