Vitamin D supplementation in elderly nursing home residents: daily supplementation compared to a loading dose and monthly supplementation, a randomised trial

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Primairy aim:-to investigate whether with a loading dose based on body weight and baseline serum 25(OH)D level more patients achieve adequate serum 25(OH)D levels compared to 800 IU a day on T 1(5 weeks) and T2 (12 weeks).-to determine the best...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36493

Source
ToetsingOnline

Brief title
VIDIN

Condition

- Other condition

Synonym
Vitamin D deficiency

Health condition

Vitamine deficienties

Research involving
Human

Sponsors and support

Primary sponsor: Liemerije in Zevenaar (verpleeghuis)
Source(s) of monetary or material Support: Alysis zorggroep

Intervention

Keyword: Colecalciferol, Loading dose, Nursing home, Vitamin D

Outcome measures

Primary outcome

Proportion of patients achieving and maintaining an adequate serum 25(OH)D

level (75 -150 nmol/l).

Secondary outcome

Proportion of patients developing a serum 25(OH)D level > 220 nmol/l.

Percentage of patients achieving an adequate serum 25(OH)D level, with the use

of a loading dose, after 5 weeks

Handgrip strength.

Distance achieved in a 2 minute walk test.

Study description

Background summary

Vitamin D deficiency is common in older persons, in particular in residents of nursing homes. This is mainly explained by the fact that older persons do not often go outside in the sunshine. On top of that the capacity of the skin to synthesize provitamin D is decreased and dietary vitamin D intake is low. Vitamin D deficiency leads to osteoporosis, falls and fractures. To prevent morbidity and mortality due to falls and fractures it seems logical to supplement vit D in order to correct the deficiency. The advised daily dose of vit D supplementation is 800 IU. Several studies showed that with this dose the

required serum 25(OH)D levels will not be reached.

Study objective

Primairy aim:
-to investigate whether with a loading dose based on body weight and baseline serum 25(OH)D level more patients achieve adequate serum 25(OH)D levels compared to 800 IU a day on T 1(5 weeks) and T2 (12 weeks).
-to determine the best consolidation treatment.

Secondairy aim:
-is a loading dose based on body weight and baseline serum 25(OH)D level safe to use in residents of nursing homes.
-is there a relation between the increase in serum 25(OH)D level and muscle strength (handgrip strength).
-is there a relation between the increase in serum 25(OH)D level and mobility (2 minute walk test).
-how many patients reach adequate vit D levels, with the use off a loading, dose after 5 weeks.

Study design

Randomised trial with 3 study groups:
Group 1a. loading dose based on body weight and baseline serum 25(OH)D level + 50.000 IU vit D3/month consolidation therapy.
Groep 1b. loading dose based on body weight and baseline serum 25(OH)D level + 25.000 IU vit D3/month consolidation therapy.
Groep 2. 800 IU vit D3/ dag.

Intervention

Group 1a. loading dose based on body weight and baseline serum 25(OH)D level + 50.000 IU vit D3/month consolidation therapy.
Groep 1b. loading dose based on body weight and baseline serum 25(OH)D level + 25.000 IU vit D3/month consolidation therapy.
Groep 2. 800 IU vit D3/ dag.

Study burden and risks

Patient time: 120 minutes in a period of 6 months, including one visit to the outpatient clinic.
Tests: hand grip strengt and 2 minute walking test will be assessed 4 times.
Blood will be drawn 4 times.

Contacts

Public
Liemerije in Zevenaar (verpleeghuis)

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6900 GA Zevenaar
NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Long term indication for living in a residential home for the elderly
Age > 65 years
Vitamin D deficiency (serum 25- hydroxycholecholecalciferol (25(OH) D3 < 50 nmol/l)
Informed consent

Exclusion criteria

Hypercalcemia (serum Ca > 2.60 mmol/l)
Hyperfosfatemia (serum PO4>2.0 mmol/l)
Ca x PO4 > 4.5
Life expectancy < 1/2 year

Multivitamin use including > 400 IE vit D
Renal dysfunction GFR< 30ml/min
malabsorption
granulomatous disease (tubercolusis, sarcoidosis)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	03-02-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL32764.091.10