Efficacy of a vitamin D dosing regimen

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21710

Source
Nationaal Trial Register

Health condition

Vitamin D deficiency, Vitamine D deficiëntie

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Medisch Centrum Leeuwarden

Intervention

Outcome measures

Primary outcome

The primary aim of this study is to determine the efficacy of the established cholecalciferol dosing regimen (a single oral loading dose of 200,000 IU cholecalciferol followed by 100,000 IU orally every 13 weeks) in obtaining and maintaining an adequate serum 25-hydroxyvitamin D level between 75 and 220 nmol/L in somatic and psycho-geriatric nursing home residents.

Secondary outcome

A second aim of this study is to assess the additional effect of the vitamin D dosing regimen on serum PTH and calcium levels, and to determine the influence of (known) variables as

possible effect modifiers on the serum 25-hydroxyvitamin D level outcome.

Study description

Background summary

Nursing home residents are at particular risk of developing vitamin D deficiency, leading to bone loss and ultimately increasing the risk of falls and fractures. Vitamin D intervention studies have shown a beneficial effect on the prevention of falls, improvement of muscle strength, and prevention of osteoporotic fractures, recommending a 25-hydroxyvitamin D level >75 nmol/L. A team of health care professionals introduced a standardized vitamin D dosing regimen for residents of 13 somatic and psycho-geriatric nursing homes in Friesland (The Netherlands), consisting of a single oral loading dose of 200,000 IU cholecalciferol followed by 100,000 IU orally every 13 weeks. The hypothesis was that with this regimen, an adequate 25-hydroxyvitamin D level of at least 75 nmol/L would be achieved and maintained, and the toxicity threshold of 220 nmol/L would not be exceeded. The primary aim of this cross-sectional observational study is to determine the efficacy of the established standardized cholecalciferol dosing regimen in obtaining and maintaining an adequate and safe serum 25-hydroxyvitamin D level. A second aim of this study is to assess the additional effect of the vitamin D dosing regimen on serum PTH and calcium levels, and to determine the influence of (known) variables as possible effect modifiers on the serum 25-hydroxyvitamin D level outcome.

Study objective

Vitamin D plays an integral role in calcium and phosphorus homeostasis. A low vitamin D status can occur as a result of reduced synthesis due to lack of sun exposure, decreased intake or absorption, increased hepatic catabolism, or decreased endogenous conversion to the active compound. Nursing home residents are at particular risk of developing vitamin D deficiency, leading to bone loss and ultimately increasing the risk of falls and fractures. Vitamin D intervention studies have shown a beneficial effect on the prevention of falls, improvement of muscle strength, and prevention of osteoporotic fractures, recommending a 25-hydroxyvitamin D level >75 nmol/L. The first measurable consequences of vitamin D toxicity are hypercalciuria and hypercalcemia, which have been observed only at 25-hydroxyvitamin levels above 220 nmol/L. To date, no study has yet described an effective vitamin D3 dosing regimen to achieve and maintain 25-hydroxyvitamin D level between 75 and 220 nmol/L in somatic and psychogeriatric nursing home residents (men and women) in a sufficiently large sample size. In July of 2010, a team of health care professionals (consisting of hospital pharmacists of Medisch Centrum Leeuwarden and elderly care physicians of Noorderbreedte) introduced a vitamin D dosing regimen for nursing home residents based on studies and evidence available at the time (the ‘Vitamin D protocol’). Motive for this initiative was the fact that it had been established that vitamin D deficiency was common in this population and that supplementation of vitamin D had substantial benefits regarding the prevention of falls and fractures. The vitamin D dosing regimen was

ultimately determined as a single oral loading dose of 200,000 IU cholecalciferol followed by 100,000 IU orally every 13 weeks (corresponding to circa 1,100 IU per day). The hypothesis was that with this regimen, an adequate 25-hydroxyvitamin D level of at least 75 nmol/L would be achieved and maintained, and the toxicity threshold of 220 nmol/L would not be exceeded. The primary aim of this study is to determine the efficacy of the established cholecalciferol dosing regimen (a single oral loading dose of 200,000 IU cholecalciferol followed by 100,000 IU orally every 13 weeks) in obtaining and maintaining an adequate serum 25-hydroxyvitamin D level between 75 and 220 nmol/L in somatic and psycho-geriatric nursing home residents. A second aim of this study is to assess the additional effect of the vitamin D dosing regimen on serum PTH and calcium levels, and to determine the influence of (known) variables as possible effect modifiers on the serum 25-hydroxyvitamin D level outcome.

Study design

The venous blood sample will be drawn within 1 week prior to the next cholecalciferol dose, 84-91 days after the previous dose.

Intervention

The drawing of a single venous blood sample, which is standard care as part of the Vitamin D protocol.

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Eligibility criteria

Inclusion criteria

The study population comprises residents of 13 somatic and psycho-geriatric nursing homes.

Nursing home residents will be screened for eligibility based on the inclusion criteria. In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Subjects must be over 18 years of age.

- Subjects must have received vitamin D supplementation according to protocol for at least 4 months (a single oral loading dose of 200,000 IU cholecalciferol followed by at least one maintenance dose of 100,000 IU after 13 weeks).

Exclusion criteria

Not applicable.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2015
Enrollment:	150
Type:	Unknown

Ethics review

Positive opinion

Date:	05-08-2016
Application type:	First submission

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
NTR-new	NL5849
NTR-old	NTR6029
Other	METC : nWMO 133

Study results