Efficacy of a vitamin D dosing regimen

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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...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21710

Bron
Nationaal Trial Register

Aandoening

Vitamin D deficiency, Vitamine D deficiëntie

Ondersteuning

Primaire sponsor: Medisch Centrum Leeuwarden
Overige ondersteuning: Medisch Centrum Leeuwarden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Not applicable.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland Status:	Anders
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	150

Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	05-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5849
NTR-old	NTR6029
Ander register	METC : nWMO 133

Resultaten