Onderzoek naar de effecten van vitamine D op de longfunctie, luchtweginfecties en lichamelijke conditie bij COPD-patiënten.

Gepubliceerd: 29-03-2011 Laatst bijgewerkt: 18-08-2022

Although vitamin D is well known for its function in calcium homeostasis and bone mineralisation, several studies have shown an effect on pulmonary function and incidence of airway infections. Vitamin D deficiency is a common problem in patients...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25037

Bron
Nationaal Trial Register

Aandoening

COPD

Ondersteuning

Primaire sponsor: VU University Medical Centre
Overige ondersteuning: VU University Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters are the serum concentration 25-hydroxyvitamin D, the pulmonary function parameters FEV1 and FVC, the incidence of airway infections, the scores on the physical performance tests and the scores on the LASA physical activity questionnaire

(LAPAQ).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Although vitamin D is well known for its function in calcium homeostasis and bone mineralisation, several studies have shown an effect on pulmonary function and incidence of airway infections. Vitamin D deficiency is a common problem in patients with COPD. As vitamin D deficiency is associated with impaired pulmonary function and a higher incidence of airway infections, supplementation with vitamin D might have positive effects on these outcomes in patients with COPD.

Objective:

To assess the effect of vitamin D supplementation on pulmonary function, the incidence of airway infections and physical performance in patients with COPD.

Study design:

Double-blind placebo-controlled intervention study.

Study population:

The study population will include 120 patients with COPD, aged between 40 and 75 years, who will be randomly allocated to one of two groups.

Intervention:

The intervention group will receive vitamin D3 1200 IU orally once a day. The control group will receive a placebo orally once a day.

Main study parameters/endpoints:

The main study parameters are the serum concentration 25-hydroxyvitamin D, the pulmonary function parameters FEV1 and FVC, the incidence of airway infections, the scores on the physical performance tests and the scores on the LASA physical activity questionnaire (LAPAQ).

Methods:

During the study there will be three visits. Measurements will be conducted at baseline before randomisation (t=0), at 3 months (t=3) and at 6 months (t=6) after randomisation. During every visit the patients will undergo spirometry, a blood sample will be drawn, a questionnaire on functional limitations will be filled in, and physical performance tests will be done. The participants will also receive a diary card to register the incidence of airway infections during the study period.

Doel van het onderzoek

Although vitamin D is well known for its function in calcium homeostasis and bone mineralisation, several studies have shown an effect on pulmonary function and incidence of airway infections. Vitamin D deficiency is a common problem in patients with COPD. As vitamin D deficiency is associated with impaired pulmonary function and a higher incidence of airway infections, supplementation with vitamin D might have positive effects on these outcomes in patients with COPD.

Onderzoeksopzet

During the study there will be three visits. Measurements will be conducted at baseline before randomisation (t=0), at 3 months (t=3) and at 6 months (t=6) after randomisation. During every visit the patients will undergo spirometry, a blood sample will be drawn, a questionnaire on functional limitations will be filled in, and physical performance tests will be done. The participants will also receive a diary card to register the incidence of airway infections during the study period.

Onderzoeksproduct en/of interventie

The intervention group will receive vitamin D3 1200 IU orally once a day. The control group will receive a placebo orally once a day.

Contactpersonen

Publiek

VU Medical Center, Department of Endocrinology,
P.O. Box 7057
P. Lips
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4440614

Wetenschappelijk

VU Medical Center, Department of Endocrinology,
P.O. Box 7057
P. Lips
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4440614

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Written informed consent;

2. Aged between 40 and 75 years;

3. Diagnosis COPD performed by the pulmonologist;

4. Vitamin D deficiency (defined as a serum 25-hydroxyvitamin D < 50 nmol/l).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe vitamin D deficiency (serum 25-hydroxyvitamin D <15 nmol/L);

2. Life expectation of less than 6 months on the basis of concurrent disease;

3. Interfering malignant diseases;

4. Serious mental impairment i.e. preventing to understand the study protocol or comply with the study aim; potentially unreliable patients and those judged by the investigator to be

unsuitable for the study;

5. Pregnant or lactating women, or subjects who intend to become pregnant within the study period.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL2697
NTR-old	NTR2827
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A