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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25037

Source
Nationaal Trial Register

Health condition

COPD

Sponsors and support

Primary sponsor: VU University Medical Centre
Source(s) of monetary or material Support: VU University Medical Centre

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

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Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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

Study results

Summary results
N/A