Effect of vitamin D supplementation on pulmonary function, airway infections and physical performance in patients with COPD: a randomized controlled trial

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON38400

Source
ToetsingOnline

Brief title
Vitamin D supplementation and pulmonary function

Condition

- Respiratory tract infections

Synonym
chronic bronchitis, Chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic obstructive, Pulmonary diseases, Respiratory tract infections, Spirometry, Vitamin D

Outcome measures

Primary outcome

The primary endpoints are respiratory muscle strength (MIP and MEP) and scores on physical performance tests.

Secondary outcome

Secondary endpoints are pulmonary function (FEV1 and FEV1/FVC), peak flow measurements, scores on muscle strength tests, incidence of exacerbations, concentrations of antimicrobial peptides in nasal seretion, bacterial and viral nasal colonization, levels of inflammatory markers in sputum, and the scores of the LASA physical activity questionnaire (LAPAQ), functional limitations questionnaire, the Short Form 12-item Health Survey (SF-12) and the EQ-5D.

Study description

Background summary

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.

Study objective

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

Study design

Double-blind placebo-controlled intervention study

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.

Study burden and risks

During the study there will be three visits. Visits will be performed at baseline before randomisation (t=0), at 3 months (t=3) and at 6 months (t=6) after randomisation.
At t=0 and t=6 patients will undergo spirometry and peak flow measurements, maximal inspratory and expiratory pressure will be measured, a blood sample will be drawn, a nasal secretion and swab sample will be obtained, questionnaires on physical activity, functional limitations and physical and mental health will be completed, and physical performance and muscle strength tests will be done. In Medical Center Alkmaar also a sputum sample will be obtained by sputum induction. At t=3 patients will perform a peak flow measurement and physical performance tests. Also, questionnaires on physical activity, functional limitations and physical and mental health will be completed. The participants will receive a diary card to registrate the incidence of exacerbations and changes in medication during the study period. The amount of blood that is taken at t=0 and t=6 is 16 mL. The participants may experience some discomfort during the physical performance tests, acquisition of nasal secretion, induction of sputum and venapunction. Participating in the study has marginal risks as the supplemented dose of 1200 IU vitamin D3 is well below the maximum advice of 2000 IU of the Health Council of the Netherlands. Participants will receive the results of the pulmonary function tests and physical performance tests after the end of the study period.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Written informed consent
- Aged between 40 and 70 years
- Postbronchodilator FEV1/FVC <70% and FEV1 <80% (GOLD-stages I-IV) and diagnosis COPD confirmed by the pulmonologist:
- Vitamin D deficiency (defined as a serum 25-hydroxyvitamin D < 50 nmol/l)
- Ability to comply with all study requirements

Exclusion criteria

- Severe vitamin D deficiency (serum 25-hydroxyvitamin D <15 nmol/L),
- Life expectation of less than 6 months on the basis of concurrent disease
- Interfering malignant diseases.
- 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.
- Pregnant or lactating women, or subjects who intend to become pregnant within the study period.
- Clinical suspicion of osteoporosis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	Nederlands Trial Register: NTR2827
CCMO	NL36386.029.11