Vitamin D/K in COPD

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26885

Source
Nationaal Trial Register

Brief title
ViDK

Health condition

COPD, chronic obstructive pulmonary disease.

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary endpoint is the difference in the rate of elastin degradation (quantified by the pDES assay) after 12 weeks of vitamin D/K vs. vitamin D/placebo supplementation.

Secondary outcome

Secondary endpoints (after 12 weeks of treatment) are: vitamin K-status (quantified by dp-ucMGP), vitamin D-status (quantified by 25(OH)D), questionnaires concerning health status

and dyspnea level, and exacerbations during the study period.

Study description

Background summary

Elastin is a unique protein providing elasticity and resilience to dynamic organs, such as lungs and arteries. Elastin is a basic requirement for both respiration and circulation. The rate of elastin degradation is accelerated in chronic obstructive pulmonary disease (COPD). Desmosine (DES) is an amino acid that is only found in elastin fibers, and plasma (p)DES levels consequently reflect the rate of elastin degradation. pDES is a strong predictor of mortality in COPD. We regard decelerating elastin degradation as an attractive novel therapeutic target in COPD. Vitamin D has anti-inflammatory properties, which might potentially have an attenuating effect on elastin degradation. However, we did not find a decreasing effect of vitamin D supplementation on pDES levels in a previous RCT, potentially due to an elastin calcifying effect of vitamin D. Elastin calcification stimulates elastin degradation and vice versa. Elastin calcification is inhibited by Matrix Gla Protein (MGP), a protein which needs vitamin K to become activated. Serum inactive levels of MGP, dephospho-uncarboxylated (dp-uc)MGP, are inversely associated with vitamin K status. Recently, we found significantly lower vitamin K status in COPD patients compared to controls. Furthermore, we found an inverse association between vitamin K-status and the rate of elastin degradation in both subjects with COPD and controls with no lung disease.

Study objective

We hypothesize that improving vitamin D and K-status by vitamin D3 plus K2 supplementation could have a favorable synergistic decelerating effect on elastin degradation.

Study design

14 weeks

Intervention

Patients are randomized between capsules of vitamin D3 plus vitamin K2 OR capsules of vitamin D3 plus capsule placebo (12 weeks).

Contacts

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Eligibility criteria

Inclusion criteria

Diagnosed with COPD based on post-bronchodilator FEV1/FVC <0.70 according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria.
Serum 25(OH)D<50 nmol/L
Age ≥40 and ≤75 years at screening visit

Exclusion criteria

Subjects using vitamin K as supplements <3 months prior to the screening visit
Use of vitamin K antagonists (i.e acenocoumarol, fenprocoumon) in 12 months prior to the screening visit
Exacerbation <6 weeks prior to the screening visit
Use of digoxin and/or thiazide diuretics
Hypercalcemia (i.e. corrected calcium for albumin >2.8 mmol/L)
Kidney stones in medical history
Severe renal failure (i.e. eGFR < 30 ml/min/1.73 m2)
Hyperparathyroidism

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):	01-10-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
N/A

Ethics review

Positive opinion

Date:	03-06-2019
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	NL7771

Register	ID
Other	CMO Regio Arnhem-Nijmegen : 2019-5482 / NL70120.091.19

Study results

Summary results
N/A