# 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 dpucMGP), vitamin D-status (quantified by 25(OH)D), questionnaires concerning health status

1 - Vitamin D/K in COPD 14-05-2025

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

#### Public

CWZ Rob Janssen

0031 24 3657944 Scientific CWZ Rob Janssen

0031 24 3657944

# **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  $\geq$ 40 and  $\leq$ 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:InterventionalIntervention model:ParallelAllocation:Randomized controlled trial

3 - Vitamin D/K in COPD 14-05-2025

Masking:	Double blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	40
Туре:	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