

Vitamin D/K in COPD

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26885

Bron

Nationaal Trial Register

Verkorte titel

ViDK

Aandoening

COPD, chronic obstructive pulmonary disease.

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

14 weeks

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	03-06-2019
Soort:	Eerste indiening

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

NTR-new

Ander register

ID

NL7771

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

Resultaten

Samenvatting resultaten

N/A