Vitamin D in non-allergic asthma.

Gepubliceerd: 08-02-2010 Laatst bijgewerkt: 19-03-2025

We hypothesize that supplementation of high doses of vitamin D in non-atopic asthmatic patients can reduce neutrophilic and/or eosinophilic airway inflammation.

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

Samenvatting

ID

NL-OMON20565

Bron
Nationaal Trial Register

Verkorte titel
PANAMA4

Aandoening

Non-atopic asthma

Niet-atopisch asthma

Ondersteuning

Primaire sponsor: Medical Centre Leeuwarden
Overige ondersteuning: Stichting Longgeneeskunde Fryslan

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The change in percentage of neutrophils and/or eosinophils in induced sputum before and 8-10 weeks after vitamin D administration.

Toelichting onderzoek

Achtergrond van het onderzoek

Non-atopic asthma is often more severe than classic allergic asthma. It is associated with neutrophilic airway inflammation and decreased steroid responsiveness and therapies other than steroids are needed. Recently, accumulating epidemiological data are linking a low vitamin D nutritional status to asthma, respiratory infections and nasal polyps. In line with the novel insights on the immune function of vitamin D, it is tempting to speculate that vitamin D may down-regulate the neutrophilic immune response in the airways while boosting innate immune defence against different microorganisms. In addition, vitamin D may play a therapeutic role in steroid resistance. We hypothesize that treatment with high dose vitamin D will decrease neutrophilic and eosinophilic airway inflammation and improve asthma control. 62 patients with predominantly neutrophilic and/or eosinophilic airway inflammation are given one high dose of vitamin D (400.000 IU) or placebo. Primary outcome will be the change in percentage of neutrophils and/or eosinophils in induced sputum. Secondary outcomes will be the effect of supplementation of a single high dose of vitamin D on the percentage of eosinophils in induced sputum, extent of sinus disease as measured on CT-sinus, pulmonary function (FEV1), levels of exhaled nitric oxide (NO), quality of life (AQLQ), asthma control (ACQ) and adverse events in non-atopic asthmatic patients and to identify potential predictors of response.

Doel van het onderzoek

We hypothesize that supplementation of high doses of vitamin D in non-atopic asthmatic patients can reduce neutrophilic and/or eosinophilic airway inflammation.

Onderzoeksopzet

1. Baseline;

2. 8-10 weeks after vitamin D administration.

Onderzoeksproduct en/of interventie

Patients recieve a single dose of vitamin D (cholecalciferole) of 400.000IU or placebo orally.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Outpatients with non-atopic asthma, determined by negative alatop;

2. Pulmonologist's diagnosis of asthma;

3. Age >=18;

4. Documented reversibility in FEV1 of >= 12%predicted OR airway hyperresponsiveness to inhaled methacholine;

5. Neutrophilic (>= 53%) or eosinophilic (>=3%) pattern of inflammation in induced sputum.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with smoking history of >10 packyears and persistent airflow obstruction (postbronchodilator FEV1<80%pred): Excluded if reversibility in FEV1 <12% predicted OR TLCO<80%pred;

2. Pregnancy;

3. Use of vitamin D analogues prior to this study;

4. Other pulmonary diseases;

5. History of kidney stones, sarcoidosis or malignancy;

6. Hypercalcaemia (corrected calcium > 2,60 mmol/l);

7. Vitamin D3 >100nmol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32451
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2088
NTR-old	NTR2205
CCMO	NL30108.099.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32451

Resultaten

Samenvatting resultaten
N/A