

# Vitamin D levels in adults with non-atopic asthma: a case-control study

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To compare the levels of vitamin D in subjects with non-atopic asthma to those in subjects with atopic asthma and those in healthy non-atopic subjects

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON34269

### Source

ToetsingOnline

### Brief title

Vitamin D in non-atopic asthma: a case-control study  
panama deel 5

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

asthma, bronchitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Leeuwarden

**Source(s) of monetary or material Support:** Stichting Longgeneeskunde Fryslan

## Intervention

**Keyword:** asthma, case-control, non-atopic, vitamin D

## Outcome measures

### Primary outcome

The difference between vitamin D levels of patients with non-atopic asthma and patients with atopic asthma and the difference between vitamin D levels of patients with non-atopic asthma and healthy non-atopic subjects .

### Secondary outcome

virus serology

Genetic tests

Pulmonary function testing: spirometry

ACQ (asthmatic patients)

Medical consumption (asthmatic patients)

Time spent outdoors

## Study description

### Background summary

Vitamin D levels have been linked to asthma and respiratory tract infections. The mechanism of this association is not yet totally understood, but vitamin D seems to have an immune modulatory effect and play a role in host defence against infections. The role of vitamin D in asthma, could especially be important in non-atopic patients, since non-atopic asthma often starts after a respiratory tract infection. Data on vitamin D levels in non-atopic asthma are lacking. By comparing vitamin D levels in non-atopic asthma patients to those in atopic asthmatics and in healthy non-atopic controls , the role of vitamin D might be better understood. We hypothesize that vitamin D levels in non-atopic asthma are lower than those in atopic asthmatics and healthy non-atopic

controls .

## **Study objective**

To compare the levels of vitamin D in subjects with non-atopic asthma to those in subjects with atopic asthma and those in healthy non-atopic subjects

## **Study design**

Case-control study

## **Study burden and risks**

Most patients with asthma can control their disease with inhalation medication and have relative few complaints. Some patients, in particular those with non-atopic asthma, can't control the disease with the usual medication and need other therapies. Recently vitamin D has raised interest, since low levels of vitamin D are related to markers of asthma severity, respiratory tract infections and impaired steroid responsiveness, all factors that are characteristic of non-atopic asthma. We hypothesize that decreased levels of vitamin D play a crucial role in non-atopic asthma and if the case, supplementation of vitamin D might become a promising alternative in this subset of asthmatic patients. However, until now data on vitamin D levels in non-atopic asthma are lacking. For a better understanding it is necessary to determine if there is a difference in vitamin D levels between non-atopic and atopic asthmatics and between non-atopic asthmatic patients and non-atopic healthy subjects.

Patients with non-atopic asthma are already included in a large cohort study. They will fill out one extra questionnaire. Participants in the other groups will also fill out this questionnaire. They will be questioned about pulmonary complaints and history. Also blood will be drawn and a short pulmonary test will be performed. The total visit will take about 30 minutes.

Altogether we think that this study can help to understand the role of vitamin D in asthma and hopefully, eventually, improve asthma therapy. Therefore we think the discomfort for study subjects is justified by the possible benefits for (non-atopic) asthmatic patients.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Group 1:

- Outpatients with non-atopic asthma, determined by negative atop
- Age \* 18 yrs
- Pulmonologist\*s diagnosis of asthma
- Documented reversibility in FEV1 of > 12% predicted OR airway hyperresponsiveness to inhaled methacholine

Group 2:

- Outpatients with atopic asthma, determined by known positive atop or skin prick test
- Age \* 18 yrs
- Pulmonologist\*s diagnosis of asthma
- Documented reversibility in FEV1 of > 12% predicted OR airway hyperresponsiveness to inhaled methacholine

Group 3:

- Subjects without pulmonary history or pulmonary complaints
- Age \* 18 yrs
- No signs of allergy and negative atop
- Normal spirometry

## Exclusion criteria

### Group 1:

- Patients with smoking history of > 10 packyears and persistent airflow obstruction (post bronchodilator FEV1 < 80%pred): excluded if reversibility in FEV1 < 12% predicted OR TLCO < 80%pred
- Pregnancy
- Use of supplements containing vitamin D analogues in the last 6 months
- Other pulmonary diseases

### Group 2:

- Patients with smoking history of > 10 packyears and persistent airflow obstruction (post bronchodilator FEV1 < 80%pred): excluded if reversibility in FEV1 < 12% predicted OR TLCO < 80%pred.
- Pregnancy
- Use of supplements containing vitamin D analogues in the last 6 months
- Other pulmonary diseases

### Group 3:

- Pulmonary history or current pulmonary complaints
- Use of supplements containing vitamin D analogues in the last 6 months
- Pregnancy

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	216
Type:	Actual

## Ethics review

Approved WMO

Date: 21-09-2010

Application type: First submission

Review commission: RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 20191

Source: NTR

Title:

### In other registers

Register	ID
CCMO	NL33519.099.10
OMON	NL-OMON20191