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

Published: 21-09-2010
Last updated: 19-03-2025

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	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

and patients with atopic asthma and the difference between vitamin D levels of

patients with non-atopic asthmaand 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

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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 alatop
- 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 alatop 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 alatop
- 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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33519.099.10
OMON	NL-OMON20191