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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20191

Source
Nationaal Trial Register

Brief title
Panama deel 5

Health condition

(non-atopic) asthma
Vitamin D

(niet-atopisch) astma
vitamine D

Sponsors and support

Primary sponsor: Research fund Medical Centre Leeuwarden
Source(s) of monetary or material Support: Stichting Longgeneeskunde Fryslan

Intervention

Outcome measures

Primary outcome

1. The difference between vitamin D levels of patients with non-atopic asthma and of patients

with atopic asthma;

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

Secondary outcome

Not applicable at this time.

If a difference is found between non-atopic asthmatics and controls, virus serology will be determined and compared between these groups and genetic tests can be performed and compared between these groups.

Study description

Background summary

Rationale:

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.

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 population:

Adult patients with non-atopic asthma will be recruited from a large cohort of non-atopic asthma patients, composed in a previous study (PANAMA 1-3).

Two other groups will be composed: One group of atopic asthma patients and one group of healthy non-atopic controls. These two groups will be matched to the non-atopic asthma group for age, sex and BMI.

Main study parameters/endpoints:

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.

Study objective

We hypothesize that vitamin D levels in non-atopic asthma are lower than those in atopic asthmatics and healthy non-atopic controls.

Study design

When patients are included, one visit is planned. No further appointments are made.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Group 1:

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

2. Age ≥ 18 yrs;

3. Pulmonologists diagnosis of asthma;

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

Group 2:

1. Outpatients with atopic asthma, determined by known positive alatop or skin prick test;

2. Age ≥ 18 yrs;

3. Pulmonologists diagnosis of asthma;

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

Group 3:

1. Subjects without pulmonary history or pulmonary complaints;

2. Age ≥ 18 yrs;

3. No signs of allergy and negative alatop;

4. Normal spirometry.

Exclusion criteria

Group 1:

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;

2. Pregnancy;

3. Use of supplements containing vitamin D analogues in the last 6 months;

4. Other pulmonary diseases.

Group 2:

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;

2. Pregnancy;

3. Use of supplements containing vitamin D analogues in the last 6 months;

4. Other pulmonary diseases.

Group 3:

1. Pulmonary history or current pulmonary complaints;

2. Use of supplements containing vitamin D analogues in the last 6 months;

3. Pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	216
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34269
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2502
NTR-old	NTR2620
CCMO	NL33519.099.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34269

Study results

Summary results
N/A