

Heterogeneity in response, genetics and inflammation and the risk for allergic and non-allergic respiratory health problems: The veterinarians' Health Study. Part-II

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON29836

Source

ToetsingOnline

Brief title

The Veterinary Health Study Cohort: VHS-cohort

Condition

- Allergic conditions
- Hepatobiliary neoplasms malignant and unspecified
- Bronchial disorders (excl neoplasms)

Synonym

allergy, hypersensitivity-type I

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: allergy / asthma, genetics, inflammatory responses, microbial (bio-aerosol) exposure

Outcome measures

Primary outcome

The incidence of allergic and non-allergic respiratory health problems and associated risk factors such as exposure to allergens, microbial bio-aerosols and infectious agents (zoonoses).

Secondary outcome

The in vitro response of full blood and PBMCs stimulated with pro-inflammatory agents.

Study description

Background summary

According to the hygiene hypothesis the decreased infectious burden during childhood has caused a misbalance between the Th1/Th2 immune balance resulting in a Th2 allergy prone status. Studies assessing the relationship between infectious diseases and allergy have both confirmed and rejected this theory. The same holds for the suggested protective effect of exposure to microbial bio-aerosols and allergy. Several studies have suggested a protective effect of endotoxin. However, in environmental and occupational studies, endotoxin exposure has been associated with acute asthma-like symptoms and bronchial hyperresponsiveness as well. More recently, interest moved beyond the Th1/Th2 paradigm of the hygiene hypothesis and focussed on a possible role of T regulatory (Treg) cells. It is hypothesised that a decrease in Treg cells could lead to reduced immune suppression of allergic reactions. The relationship between microbial stimulation, Treg cells and the effect on allergy is still unclear although the regulating influence of infectious and non-infectious

microbial exposure on the development of allergy implies that the pathogen recognition receptors (PPRs) on cells of the immune system recognizing pathogen associated molecular patterns (PAMPs), and genes encoding these PPRs might play an important role. Inconsistent results have been reported on innate immunity associated gene polymorphisms and the presence of asthma and allergy. Veterinarians are potentially exposed to allergens, endotoxin and zoonotic agents. Previously, prevalence rates ranging from 17 to 66% for self-reported atopic and allergic diseases have been described in veterinarians. A Dutch survey among veterinarians showed that the mean dust and endotoxin exposure was high in swine, poultry and cattle practitioners and relatively low in companion animal practitioners. A study in animal-health technology apprentices starting exposure to laboratory animals showed an incidence of 8.9% of work-related sensitisation and an incidence of occupational asthma of 2.7%. Sensitisation, symptoms and disease occurred in the first 2 to 3 years after exposure to laboratory animals began and predictors of sensitisation were atopy, nasal and respiratory symptoms in the pollen season and number of contact hours with rodents.

Study objective

The main aim of this follow-up study is to assess the incidence of respiratory disorders, like allergy, asthma and asthma like-syndrome, in association with the interaction of environmental and genetic risk factors in veterinary students. In order to study this, both health outcomes and environmental, genetic and intermediate factors such as inflammatory markers need to be established.

Study design

A population-based prospective follow-up study is performed among first year veterinary students. For the duration of three years, all first year veterinary students (n=225/year) are contacted to participate in the follow-up study that will follow the students during the course of their study, being at least 6 years. At baseline every student is asked to fill out a baseline health questionnaire, to give blood and to take part in a baseline health investigation. This health investigation consists of several tests to establish lung function (spirometry, bronchial hyperresponsiveness test and NO concentration measurement in exhaled air). Furthermore a nasal swab will be taken at baseline and stored frozen to possibly test, in a later stage when methods to do so are developed, for nasal carriage of infectious micro-organisms.

In the following years, each student is contacted annually to fill out the follow-up questionnaire and for a blood draw, the first to verify changes in health symptoms and the latter to verify changes in serological outcomes, like atopy. Additionally, nasal swabs will be collected and stored annually to study changes in nasal carriage of infectious micro-organisms.

A nested case-control study is performed on the basis of the outcomes of the questionnaire. Cases and incidence density sampled controls will be invited to repeat the health investigation. Cases are defined by the answer yes to a minimum number of respiratory and allergic health complaints suggestive for allergy, asthma or asthma-like disorder. Controls, not reporting these symptoms will be selected in a 1:2 ratio compared to the number of cases.

Study burden and risks

Filling out a questionnaire is hardly associated with any burden or risk. The measurements performed during the health investigation and taking blood give light burden but no real additional risks, bearing in mind that all performed tests are standard diagnostic tools used in daily clinical practice. The benefit for participating students is the gaining knowledge of exposure and associated health problems that can occur during veterinary education. With this information work methods can be changed, thereby decreasing exposure and decreasing associated health problems.

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

The inclusion criteria are being a first year veterinary student at Utrecht University and being 18 years of age or older. Younger students will be included once they have reached the age of 18.

Exclusion criteria

Not able to read the Dutch language and therefore not able to fill out the questionnaire.
Students below the age of 18 years will be excluded

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 20-09-2006

Enrollment: 675

Type: Actual

Ethics review

Approved WMO

Date:	05-09-2006
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL12032.041.06