HITEA: "Health Effects of Indoor Pollutants: Integrating microbial, toxicological and epidemiological approaches"

Published: 17-02-2009
Last updated: 06-05-2024

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

Summary

ID

NL-OMON32234

Source
ToetsingOnline

Brief title
HITEA: Indoor air quality in primary schools and health

Condition

- Bronchial disorders (excl neoplasms)

Synonym
respiratory tract inflammation and obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,CEFIC (European Chemical Industry Council). CEFIC is een samenwerkingsverband tussen zowel grote als kleine bedrijven in de chemische industrie. Het doel van het CEFIC is het stimuleren van wetenschappelijk onderzoek op het gebied van de interactie tussen chemicaliën, de menselijke gezondheid en het milieu. Eurochlor is de tak binnen CEFIC die de chloorverwerkende industrieen vertegenwoordigt.,Europese Unie;Nederlandse Astmafonds;CEFIC (Euro Chlor)

Intervention

Keyword: exposure to biological agents, indoor air quality of schools, mold and moisture problems, respiratory effects

Outcome measures

Primary outcome

- To characterize the microbial, immunological, toxicological, and

dampness-related properties of indoor air in school buildings in the

Netherlands;

- to study the relation between the different obtained exposure measurements in

schools: ventilation, CO2 and allergens levels, moisture and microbial

components;

- to study the prevalence of respiratory symptoms and specific sensitization to

environmental allergens in school children;

- to reveal the health effects associated with indoor air exposures in school

children and teachers;

- to study the mechanisms underlying the health effects;

In addition we want to evaluate the effect of swimming pool attendance on

respiratory health of school children. Therefore, we will study:

- the effect of swimming pool attendance and exposure to trichloramine in swimming pool air on self reported respiratory health symptoms and lung function measurements;

- the influence of swimming pool attendance and exposure to chloramine in swimming pool air on surfactant associated proteins A and B (SP-A and SP-B) and 16 kDA Clara cell protein 16 (CC16) levels in blood of school children;

- the relationship between surfactant associated proteins A and B (SP-A and SP-B) and 16 kDA Clara cell protein 16 (CC16) levels in blood and respiratory health symptoms and lung function.

Secondary outcome

-

Study description

Background summary

Indoor air pollution in public buildings is an emerging issue. Respiratory health of children may be affected by exposure to chemical and biological agents in the indoor environment. Studies in other European countries have shown that allergy and asthma at school age may be associated with exposure to microbial agents, allergens and irritants from swimming pools. These factors have not been studied in Dutch school age children extensively and insight in school air quality from larger scale studies is completely lacking. Some smaller scale studies have indicated that school air quality by measurement of CO2 levels also is an issue in Dutch schools because of modern building technologies and choice of building sites near busy traffic areas. However, information about levels on respiratory hazards including microbial exposure, allergens and irritants is lacking.

Study objective

The overall aim of the study is to identify the role of indoor biological and chemical agents that lead to respiratory, inflammatory and allergic health impacts in school aged children. The focus is on microbial exposures due to

dampness problems of buildings; in addition, the role of allergens, chemicals, cleaning agents, traffic exhaust and poor ventilation will be studied. As some important aspects are difficult to study among children (e.g., nasal lavage, breath condensate sampling), adults with similar exposures are also included. The four essential issues are: the extent of the dampness problem in schools, detailed characterization of the exposure to indoor school and pool environment, measurement of the health effects during and without the exposure (after summer holidays), and clarification of the mechanisms of the health effects.

Study design

Six schools in the region of Utrecht will be selected, representing moisture damaged (n=4) and control schools (n=2). Lung function measurements and blood will be taken from all pupils aged between 6 and 12 (baseline survey; t=0). The goal is to include 1500 students for health measurements. Parents-administered questionnaires will be distributed among the pupils.
Pupils with symptoms highly suggestive of asthma (based on history of asthma, recent symptoms treatment and lung function) will be identified. A randomly selected sub-sample of these children (n=180; 6 schools x 30 pupils) will be considered for the longitudinal part of the HITEA study. In these children, lung function and exhaled NO will be determined an additional 3 times (at the end of term [t=1], after summer holidays [t=2], and at the end of the following fall term [t=3]).
The teachers* health will also be assessed in the longitudinal study. At three moments in time ([t=1], [t=2], [t=3]) respiratory health will determined in 60 teachers (6 schools x 10 teachers) by spirometry tests, a symptom questionnaire, measuring exhaled NO, assessment of inflammatory markers in nasal lavage fluid and exhaled breath condensate, and measurements of specific sensitization in peripheral blood (serum) samples (only at t=1).

Study burden and risks

This is an observational study and participants will not be experimentally exposed to agent concentrations. Only current exposure to concentrations in indoor air of the daily environments will be registered, so no health risks due to exposure will be present. Increased insight in the air quality can help to improve the understanding of possible measures that are needed to improve the air quality.
The health risks of lung function testing, blood sampling, measuring exhaled NO and measuring exhaled condensed breath and nasal lavage are negligible. Therefore, additional insurance for subjects participating in the study is not needed. Each health measurement session wil take about 5-10 minutes in children, and a maximum of 30 minutes in teachers. So the tests will take 5-10 minutes time from 1320 children, 20-40 minutes time (4x 5-10 minutes repeated measurements) from 180 children, and 3x 30 minutes=1.5 hour time from the

teachers. Completing the questionnaire will take about 10 to 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

primary school children from group 3-8 and their teachers.
For the longitudinal part: primary school children from group 3-7 with symptoms highly suggestive of asthma and teachers.

Exclusion criteria

Primary school children from group 1 and 2

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):	02-03-2009
Enrollment:	1560
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL23507.041.08