Risk of Airborne Particulate matter: a Toxicological and Epidemiological hybrid Study

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The aim of the project is to investigate the effects of five contrasting air pollution scenarios on respiratory and cardiovascular health of young healthy volunteers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON32662

Source
ToetsingOnline

Brief title
RAPTES

Condition

- Haematological disorders NEC
- Cardiac disorders, signs and symptoms NEC
- Bronchial disorders (excl neoplasms)

Synonym
respiratory tract inflammation, thrombogenesis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Rijksinstituut voor Volksgezonheid en Milieu

(RIVM)

Intervention

Keyword: acute health effect, air pollution, cardivascular health effects, respiratory health effects

Outcome measures

Primary outcome

Respiratory and cardiovascular health will be assessed before and after the exposure. These will include recording of symptoms, spirometry (peakflow, FEV1, FVC, FEF25-75), nasal lavage, exhaled NO and CO, blood pressure, oxygen saturation in blood, heart rate, and blood sampling. Plasma samples and nasal lavage will be analyzed on inflammation markers.

Secondary outcome

We will administer a time activity questionnaire to assess exposure to indoor sources (e.g. smoking, cooking), participation in traffic, and time spent outdoors. These measurements will be used to document the relative contribution of pre- and post experiment exposures, compared to exposure during the experiment.

Study description

Background summary

Numerous epidemiological studies have demonstrated health effects related to short- and long-term exposure to elevated concentrations of ambient particulate matter (PM). Well known is the association with respiratory and cardiovascular effects. It is not clear, however, which specific characteristics of PM are responsible for the observed effects, e.g. particle number, size, composition, oxidative capacity.

Study objective

The aim of the project is to investigate the effects of five contrasting air pollution scenarios on respiratory and cardiovascular health of young healthy volunteers.

Study design

A panel of volunteers will participate in a total of 5 hours exposure to air pollution at 5 different outdoor locations in the Netherlands. During this exposure they will be asked to engage in mild-moderate exercise for a total of 1.7 hours (100 minuts of cycling on a hometrainer, spread over 5 hours). The locations have high contrasts in, and low correlation among, major PM components and their oxidative capacity, as established in a screening study. Respiratory and cardiovascular health will be assessed before and after the exercise. Air pollution, exposure to particulate matter and gasouses pollutants, will be also characterized on-site.

Thirty-two healthy volunteers, 18-35 years old, will be recruited for the study. Each potential participant will be asked to complete a screening questionnaire prior to the enrolment in the study. Participant that meet the in- and exclusion criteria are invited for a pre-test. Subsequently, each volunteer will be tested seven times for the main study (exercise on location).

Study burden and risks

Pre-test (4 uur): record baseline information for every volunteer. To this end we will use a questionnaire, a blood pressure measurement and a blood sample. Furthermore, all test of the main study (including biking) will be performed onces. This will be used to show potential participants the study procedure.

Main study: maximum of 7 measurements (11,5 hours per measurement) in de period of spring 2009 until autum 2009. There will be at least 2.5 weeks inbetween two measurements. A mesurement exists of a 5-hour exercise scheme: 20 minutes of cycling on a hometrainer alternated with 40 minutes resting. The following test will be performed before and after the exercise:
- Time-activity questionnaire: 2 hours before, and 18 hours after the exercise (18 hours is the next morning)
- Blood pressure: 2 hours before, and 2 and 18 hours after the exercise
- Symptom questionnaire: 2 hours before and directly before; directly after, 2 and 18 hours after the exercise
- Long function: 2 hours before and directly before; directly after, 2 and 18 hours after the exercise
- Nitric oxide in exhaled air: 2 hours before and directly before; directly after, 2 and 18 hours after the exercise
- Carbon monoxide in exhaled air: 2 hours before and directly before; directly

after, 2 and 18 hours after the
exercise
- Nasal lavage: 2 hours before, and 2 and 18 hours after the exercise
- Blood sample: 2 hours before, and 2 and 18 hours after the exercise
- Pulse and oxygen saturation: continiously during the exercise

Contacts

Public
Universiteit Utrecht

Postbus 80.177
3508 TD Utrecht
Nederland
Scientific
Universiteit Utrecht

Postbus 80.177
3508 TD Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy, non smoking, 18-35 years of age, living in students housing facilities at the campus of Utrecht University (de Uithof), good understanding of the Dutch language

Exclusion criteria

lifetime diagnosis asthma or COPD
recent wheeze, shortness of breath, chronic cough
history of high blood pressure, angina pectoris or myocardial infarction
medication for respiratory or cardiovascular disease
diabetes mellitus
obesity
smoking or living in a household with a smoker
pregnancy

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):	03-02-2009
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2008
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	NL24102.041.08