Health effects due to inhalation of ultrafine particles in healthy volunteers. Multiple short-term exposures to UFP near Schiphol Airport. A cross-over study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON46447

Source
ToetsingOnline

Brief title
Health effects due to inhalation of ultrafine particles

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Cardiac arrhythmias
- Bronchial disorders (excl neoplasms)

Synonym
airway narrowing, Bronchial obstruction, heart function

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Air traffic, Health effects, Road traffic, Ultra fine particles

Outcome measures

Primary outcome

- Exhaled Nitric Oxide (FeNO)

- Blood pressure

Secondary outcome

- Lung function (Flow/Volume)

- Oxygen saturation

- Heart rate

- ECG

- SpiroNose measurement

- Low molecular metabolites in urine

Study description

Background summary

Air pollution in general is known to cause pulmonary and cardiovascular health effects. Ultrafine particles (UFP) (< 0.1 µm) comprise a large part of particulate material from air pollution. The concentration of ultrafine particles near airports is increased. Concern is rising for the health effects of people living in the vicinity of Schiphol Airport.

Study objective

We hypothesize that the toxic potency of UFP from air traffic is comparable to road traffic after inhalation by healthy humans. Therefore, we aim to:
* Identify acute effects of short-term inhalation of ultrafine particles right next to Amsterdam Schiphol Airport (dominated by aviation exhaust but also with contributions from road traffic exhaust) by assessing pulmonary, cardiovascular, and oxidative stress parameters
* To relate the effects with total UFP (inhaled as well as estimated dose) as well as to UFP apportioned to aviation and road traffic.

Study design

This will be a single center, randomized, double blind, cross-over study in healthy volunteers.

Intervention

Volunteers will be exposed for four separate days to ultrafine particles present in local air drawn into a mobile exposure laboratory (MAPCEL) of the RIVM. Exposure will take place in the proximity of air traffic activity, with, depending on the wind direction also an impact of near road traffic. The volunteers will be blinded for the type of exposure and they will do intermittent exercise on a bicycle ergometer during the exposure period, which will be 5 hours per exposure day. There will be a minimum of 2 weeks between exposure days and each volunteer will be exposed for at least 4 times. In case of low exposures during the first 4 visits, the RIVM can decide to schedule another fifth or sixth exposure (after consent of the subject).

Study burden and risks

Burden:

1 screeningsvisit (1,5h): medical background, blood pressure, heart rate and saturation measurement, ECG, long function and exhaled breath measurement.

4 study days (10h/day) with at least 2 weeks in between
Possibly 5 or 6 study days, in case of low exposures in the first 4 visits (as judged by the RIVM) and after consent of the subject

Study day:
- pré exposure: urine sample, blood pressure, heart rate and saturation measurement, ECG, long function and exhaled breath measurement.
- exposure: 5 hours in MAPCEL nearby Schiphol Airport. Subjects cycle 1x20 minutes/hour on a hometrainer
- post exposure: blood pressure, heart rate and saturation measurement, ECG, long function and exhaled breath measurement.
- day after exposure: urine sample

No invasive measurements

Risks: No expected health risks

Contacts

Public
RIVM

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Healthy subjects between 18 and 35 years of age
* Baseline FEV1 > than 80% of predicted value
* Able to communicate well with the investigator and to comply with the requirements of the study
* Written informed consent
* No current smoking for at least 1 year and less than 5 pack years of smoking history.

Exclusion criteria

* History of pulmonary or cardiovascular events/diseases
* History of hay fever/pulmonary disease
* Use of medications that affect pulmonary or cardiovascular parameters
* History of enhanced bleeding tendency
* A history of smoking within the last 12 months, or regular consumption of greater than three units of alcohol per day
* Administration of any investigational drug within 30 days of study initiation
* Current pregnancy
* Donation of blood within 60 days, or loss of greater than 400 ml of blood within 12 weeks of study initiation
* Respiratory tract infection in the last 6 weeks before or during the study
* Use of alcohol, tobacco and caffeine-containing drinks in the 24 hours before measurement
* History of serious drug-related reactions, including hypersensitivity
* Residency or daily work/study activities within 100 meters of a busy road or 300 meters from a freeway.
* Residency or daily work/study activities in the area of Schiphol Airport or within distance of 2 kilometres of the Schiphol area.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27988
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63438.018.17
Other	NTR 28094
OMON	NL-OMON27988