No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

# Summary

## Source

NTR

## Health condition

Lung function
Heart function
Inflammation
Oxidative stress

## Sponsors and support

| | |
|---|---|
| Primary sponsor : | Academic Medical Center Amsterdam in collaboration with the National Institute for Public Health and the Environment (RIVM) |
| Source(s) of monetary or material Support : | National Institute for Public Health and the Environment (RIVM) |

## Intervention

## Outcome measures

## Primary outcome

The primary endpoints are exhaled Nitric Oxide (FeNO) for inflammation and blood pressure for the cardiovascular effects

## Secondary outcome

Secondary outcome parameters are:

- Lung function (Flow/Volume)

- Oxygen saturation

- Heart rate

- ECG

- SpiroNose measurement

- Oxidative stress markers in urine collected shortly before and 24 hours after on site exposure

- Molecular markers as measured in peripheral blood

# Study description

## Background summary

Rationale: 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.

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.

Study population: 20 healthy human volunteers, 18 – 35 years' old

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.

Main study parameters/endpoints: The primary endpoints are changes in exhaled Nitric Oxide (FeNO) for inflammation and Blood Pressure for the cardiovascular effects. Secondary endpoints comprise additional lung function tests, heart rate, ECG, inflammation and oxidative stress parameters in peripheral blood, and oxidative stress parameters in urine.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden associated with this study includes a screening visit, during which an intake interview, a physical examination, and lung function will be done. At an exposure day, participants will come to the AMC for baseline measurements of lung function, cardiovascular parameters, urine sample and blood draw (15 mL). Then they will be transported to the exposure location, be exposed for 5 hours in which they perform intermittent, moderate exercise. After the exposure period, they will be transported back to the AMC for repeated measurements. The morning after the study day, a second urine sample will be collected by the participant and sent to the AMC. Each volunteer will receive 4 exposure days with at least 2 weeks in between. We believe the burden of this study is mainly an investment of time.

Relevance: This study will report on the health effects of inhalation of total and air traffic derived ultrafine particles in comparison with road traffic derived particles, and filtered air. Thereby, answering several questions considering the risks of air traffic exhaust in relation to road traffic exhaust. As such, we consider the balance between risks and discomfort for the study subjects (low) and the possible benefit for society in the future acceptable.

## 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

Screening visit

Study days:

- Baseline measurements T = 0h

- Exposure for 5 hours

- Post-exposure measurements T = 8h

- Post exposure urine sample T = 2h4

## Intervention

4 exposures to ambient air with ultrafine particles derived from road traffic and/or air traffic.

Exposure will take place in a mobile exposure laboratory for 5 hours/day during which the participants will perform moderate exercise.

# Contacts

**Public**
Marije Lammers
Amsterdam
The Netherlands
**Scientific**
Marije Lammers
Amsterdam
The Netherlands

# Eligibility criteria

## Inclusion criteria

• Healthy subjects between 18 and 35 years of age

• No clinically significant findings during physical examination

• 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

• 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

• 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 kilometers of the Schiphol area. (See Figure 2; map of areas for exclusion)

# Study design

## Design

| | |
|---|---|
| Study type : | Interventional |
| Intervention model : | Crossover |
| Masking : | Double blinded (masking used) |
| Control : | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status : | Pending |
| Start date (anticipated) : | 01-01-2018 |
| Enrollment : | 20 |
| Type : | Anticipated |

# Ethics review

Not applicable

| | |
|---|---|
| Application type : | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 46447
Bron:
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL6569 |
| NTR-old | NTR6955 |
| CCMO | NL63438.018.17 |
| OMON | NL-OMON46447 |

# Study results