Invloed van ultrafijn stof op de gezondheid van gezonde vrijwilligers: "Klinische studie ultrafijn stof rondom Schiphol"

Gepubliceerd: 25-10-2017 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27988

Bron
NTR

Aandoening

Lung function
Heart function
Inflammation
Oxidative stress

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam in collaboration with the National Institute for Public Health and the Environment (RIVM)
Overige ondersteuning: National Institute for Public Health and the Environment (RIVM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Screening visit

Study days:

- Baseline measurements T = 0h

- Exposure for 5 hours

- Post-exposure measurements T = 8h

- Post exposure urine sample T = 2h4

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46447
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten