

# Respiratory health effects of short-term traffic-related air pollution exposure in cyclists.

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The objective of the study is to investigate respiratory health effects of exposure to traffic-related air pollution during commuting by bicycle.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30082

### Source

ToetsingOnline

### Brief title

Not applicable.

### 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

## Intervention

**Keyword:** cyclists, Respiratory health effects, short-term exposure, traffic-related air pollution

## Outcome measures

### Primary outcome

- Exhaled NO.
- Forced Expiratory Volume during the first second of expiration (FEV1).

### Secondary outcome

- Forced Vital Capacity (FVC).
- Peak Expiratory Flow (PEF).
- Symptoms.

## Study description

### Background summary

There is a scarce amount of knowledge on health effects of short-term, journey-time exposure to traffic-related air pollution. While the researches on short-term exposure to air pollution from traffic have been done in recent years, to our knowledge there exists no study that investigated the health effects of such type of exposure in a real-world situation.

### Study objective

The objective of the study is to investigate respiratory health effects of exposure to traffic-related air pollution during commuting by bicycle.

### Study design

- 4-week study period.
- Two routes - Route 1 (leading from the centre of Utrecht city to IRAS location at Uithof, largely along major roads) and Route 2 (designed to create contrast in the exposure to traffic-related air pollution. It will go from the centre of the city to IRAS as well, but through green areas and small roads distant from main roads).

- 20 voluntary participants, divided into four groups (a, b, c, d) of 5. Each group will travel the selected routes eight times in total - four times Route 1 and four times Route 2. Two groups will travel simultaneously on different routes for 1 hour, during morning rush hours (08:00-09:30), twice a week, during 4 weeks study period. The measurements of exposure to traffic-related air pollution will be made on both routes.
- Pre- and post-exposure health measurements will be conducted. The participants will fill in a baseline questionnaire regarding their respiratory health status. During the study their lung function (spirometry) and exhaled NO will be evaluated, they will be also filling in a symptom questionnaire.
- The study design results in 160 measurements in total.

### **Study burden and risks**

There is a potential risk of traffic accidents during cycling in the morning rush hours. We will try to minimize this risk by instructing the participants to strictly follow the existing traffic rules and regulations.

## **Contacts**

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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, non-smoking students and workers of Utrecht University living in the Utrecht city centre and cycling regularly to the Uithof, not exposed to other sources of air pollution (e.g. performing laboratory work, etc.) before afternoon's health status evaluation (6 hours after exposure).

### Exclusion criteria

The exclusion criterion of this study is a presence of asthma, or chronic obstructive pulmonary disease (COPD).

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 11-04-2007

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 28-11-2006

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	NL13063.041.06