Acute immunotoxicological effects of traffic-related micro- and nanoplastics in urban air.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON51750

Source
ToetsingOnline

Brief title
PETE: micro- and nanoPlastic Exposure and immuno-Toxicological Effects

Condition

- Allergic conditions
- Bronchial disorders (excl neoplasms)

Synonym
immunotoxicological health; inflammation;

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: immunotoxicology, micro- en nanoplastics, traffic exhaust

Outcome measures

Primary outcome

The main study endpoints are MNP levels in blood and changes in inflammatory markers (i.e. blood leukocytes, cytokines) and antioxidant defence levels in blood.

Secondary outcome

Secondary endpoints include lung function (FEV1, PEF), changes in inflammatory markers in saliva and respiratory symptoms.

Study description

Background summary

There is increasing concern about micro- and nanoplastics (MNPs) in the environment. One of the predominant sources releasing MNPs into the atmosphere is motorized road traffic tyre wear. No research has thus far studied uptake in the blood stream and potential health effects of airborne MNPs. This research will therefore investigate the concentrations of MNPs people are exposed to, and which short term health effects may occur in urban settings.

Study objective

The main objective is to study presence of MNPs in blood and short-term changes in blood leukocytes, inflammatory markers and the anti-oxidant defence system, in association with traffic-related microplastic exposure in healthy young adults. Secondary outcomes are changes in respiratory function and inflammatory markers in saliva.

Study design

The study has a controlled repeated measures design, assessing the presence of MNPs in blood and short-term immuno-toxicological health effects in healthy people aged 18 - 45 years exposed at three locations in Utrecht at the same

time-of-day: highway, stop-and-go traffic location and an urban parc. Exposure will take 4 hours and include intermittent exercise. The highway and the stop-and-go location probably have a high contrast in MNPs. During these sessions, MNPs will be collected on filters for physicochemical analysis, and the presence of other traffic-related major air pollutants (black carbon (BC), ultrafine particles (UFP)) will be continuously monitored. Blood and saliva will be collected before, immediately after and 17 hours after each session. Furthermore, before and immediately after each session, we will perform lung function measurements and ask the volunteers to fill in a questionnaire regarding respiratory symptoms.

Study burden and risks

The volunteers will be asked to participate in 3 separate sessions of each 7 hours, over the course of 5 months, amounting to about 21 hours in total. In two sessions, exposure to MNPs, predominantly from abrasion of tyres from vehicles will occur, in varying concentrations. The third session, which will take place in an urban parc with low concentrations of MNPs from tyres, will have an identical set-up to the other sessions. All tests will be performed by trained project-employees and experts for the collection of blood. We are not sure what the health risks are of exposure to traffic-related MNPs, since this is the topic of this study. However, we do not expect additional risks compared with the normal situation. For example, food delivery cyclists are exposed to similar concentrations for similar or even longer durations, also while cycling. Participants will not personally benefit from the scientific outcomes of the study. It is expected that the people are interested to participate in the study, due to the emerging global environmental awareness and health concerns of plastic pollution. As an appreciation for their participation, the participants will receive a gift certificate of 175 euros, once they complete the three sessions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy young adults, aged 18 - 45 years, living in the neighborhood of the Utrecht Science Parc.

Exclusion criteria

smoking, respiratory inflammation (i.e. COPD or asthma), cardiovascular disease, or the use of anti-inflammatory/respiratory/cardiovascular medication.

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):	18-07-2022
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	17-06-2022
Application type:	First submission
Review commission:	METC NedMec

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	NL80294.041.22