The Actionable eUropean ROadmap for early-life health Risk Assessment of micro- and nanoplastics (AURORA) Household Plastics Study

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Primary Objective: 1) To assess determinants of circulating MNP levels in Dutch females of reproductive age, including the relative contribution of indoor sources, food packaging and preparation methods to MNP and plastic-associated chemical body…

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

Summary

ID

NL-OMON56104

Source
ToetsingOnline

Brief title
Aurora Household Plastics

Condition

- Other condition

Synonym
microplastic exposure assessment

Health condition

No health outcomes will be evaluated, only MNP exposure levels

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: European Committee

Intervention

Keyword: chemical risk assessment, human exposure assessment, microplastic

Outcome measures

Primary outcome

Levels of MNPs in the body, including MNP-associated chemicals. Main plastics

of interest are polystyrene (PS), polyvinyl chloride (PVC), polyethylene

terephthalate (PET), polyamide (PA), polyethylene (PE), and polycarbonate (PC).

We will evaluate circulating blood levels and excreted urinary levels.

Secondary outcome

MNPs in household dust

Study description

Background summary

The scale of micro- and nano- plastic (MNP) pollution is becoming increasingly clear, yet little is known about human exposures and ultimately human health outcomes. Microplastics are plastics with length of 5mm or less, and nanoplastics are plastics particles smaller that 100µm. This study is part of the EU-funded H2020 AURORA project and will contribute to an actionable European roadmap for early-life health risk assessment of MNPs to support regulation of MNPs and the products and processes that generate secondary MNPs, and development of safer alternatives. Overall, the AURORA project will focus on the toxicological and health effects of MNP exposures in pregnant women as well as their offspring in foetal life and (early) childhood, because these periods are critical for development and health later in life and are thus periods of heightened vulnerability to environmental insults. It has been recently shown that MNPs are present in blood (Leslie et al., 2022) and have

the potential to cross the placental barrier, underlying the urgent need to understand the impact of MNPs on reproductive and early-life health (Braun et al., 2021; Grafmueller et al., 2015).

There is clear evidence that plastic chemicals migrate from food contact articles into food and translocate via the gastrointestinal tract into the body (Muncke et al., 2020). Although the adverse health effects of specific plastic-associated chemicals are increasingly being documented, the impacts of MNPs (i.e., particles and fibers) remain uncertain. MNP exposure via the diet is considered as one of the main exposure pathways and warrants further investigation (Wright & Kelly, 2017). In previous studies, MNPs have been detected in food and beverages including bottled water, honey, milk, fruits, vegetables, sugar, and sea salt (Diaz-Basantes et al., 2020; Oliveri Conti et al., 2020; Toussaint et al., 2019). Furthermore, microplastics have been detected in the faeces of adults and meconium of newborns, demonstrating that MNPs are in fact ingested at detectable levels (Braun et al., 2021; Schwabl et al., 2019). Therefore, it is very relevant to understand exposures from food packaging. Little is known about internal levels of MNPs, making this research novel.

Another significant exposure pathway to MNPs is inhalation (Ageel et al., 2021). High levels of indoor microplastic fallout from gradual degradation of household products, including textiles and clothing, makes inhalation a significant MNP exposure route (Catarino et al., 2018). For this reason, household dust will be collected, and determinants of levels of MNPs in household dust, and correlations between levels of MNPs in household dust and internal levels of MNPs will be investigated.

We will recruit volunteers for this study in collaboration with Utrecht University. Since this is a novel research area, we will gain valuable insights by looking at this population. Given the current limited understanding of MNP exposures, this study will contribute valuable insights about the sources of MNPs contributing most to human exposure. This study aims to investigate the relative contribution of determinants of MNP and plastic-associated chemical body burdens, including indoor sources, food packaging and preparation methods.

Study objective

Primary Objective:
1) To assess determinants of circulating MNP levels in Dutch females of reproductive age, including the relative contribution of indoor sources, food packaging and preparation methods to MNP and plastic-associated chemical body burdens.

Secondary Objectives:
1) To describe plastic usage frequency and patterns in Dutch females of reproductive age

2) To measure house dust levels of MNPs and evaluate if correlated with circulating MNP levels in blood and excreted MNP levels in urine.

Study design

We will perform an observational study among 100 females of reproductive age. We will include female volunteers of reproductive age (18 - 45 years) who reside within 70 km of Utrecht. After recruitment and providing informed consent, the participants (100 females) will be asked to fill out out a questionnaire describing factors which may contribute to their plastic exposure (including household characteristics, food packaging, etc.) and potential covariates. A venous blood, morning void urine sample, and evening urine sample will be collected at baseline and after three months (i.e., the completion of the study). Participants will be provided with a glass petri dish to set at home for a 30-day passive dust sample collection at baseline and again after three months.

Study burden and risks

Burden: All participants will fill in a survey at baseline and a follow up questionnaire after three months. There will be two blood samples drawn and two urine samples collection. There is limited burden associated with providing blood and urine samples.
Risks: There are negligible risks for participants.
Benefit: The study has no direct benefit to the participants. The study will deliver relevant insight into the body burden of MNPs. This will, in turn, contribute to future risk assessment of MNPs.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Female of reproductive age (18~45 years)
Reside within 70 km of UMCU
Able to provide informed consent

Exclusion criteria

Insufficient literacy skills to communicate and complete the survey (in Dutch or English)
No internet access

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	12-07-2023
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-03-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-06-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-09-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-04-2024
Application type:	Amendment
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	NL81071.041.22