The uptake and excretion of a single oral dose of 1 µm [14C]-labelled polystyrene microplastic particles in healthy volunteers using a microdose approach

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57422

Source
ToetsingOnline

Brief title
Oral 14C-Microplastic ingestion

Condition

- Other condition

Synonym
Uptake and excretion of polystyrene-macroplastic particles

Health condition

opname en excretie van oraal toegediende C14 gelabelde polystyreen-microplastic deeltjes

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: ZonMw Momentum 2.0

Intervention

Keyword: excretion, Microplastics, uptake

Outcome measures

Primary outcome

Quantitative measurement of the biokinetics (i.e. absorption, distribution, and

excretion) of a single oral microdose (100 µg) of 1 µm [14C]-labelled PS-MP

Secondary outcome

Not applicable

Study description

Background summary

Micro- and nanoplastics (MNPs, plastic particles < 5 mm) are increasingly found in food, water and air. Despite research advances in recent years, we still need to learn more about their biokinetics in the human body. In recent years, the Netherlands Organisation for Health Research and Development (ZonMw) funded several *breakthrough* projects to address the most urgent knowledge gaps in the field of MNPs and human health, which were consequently integrated in one large research initiative called the Microplastics and Human Health consortium (MOMENTUM). The overall aim of this project is to assess the potential human health risks of MNPs. A main objective of the project is to perform a provisional risk assessment of MNPs, largely based on the results of in vitro toxicity studies. To extrapolate effects observed in in vitro models the used MNP concentration in vitro need to be extrapolated to an external (human) exposure. Such an extrapolation can be facilitated by so-called toxicokinetic models. The quality of the predictions based on such model need to be benchmarked against in vivo data. Currently no data from a human toxicokinetic study is available. Some data that suggest the presence of MNP in human blood or tissues are available, however for these studies the (route of) exposure is

unknown and has not been quantified. Therefore, a human MNP microdosing study is now proposed.

Study objective

The aim of this study is to characterize the internal 1 µm polystyrene microplastic (PS-MP) exposure in various human tissues in healthy volunteers. For this, the uptake and excretion of a single microdose of 1 µm [14C]-labelled PS-MP is investigated using an extremely sensitive Accelerator Mass Spectrometry (AMS) for the analysis (as performed in METC P2309, NL84060.028.23). By labelling 1 *m PS-MPs with 14C (a universal labelling technique in which all 12C atoms in the molecule are replaced by 14C atoms), we can trace the labelled PS-MPs in body samples (blood, urine and faeces).

Study design

Single centre, non-randomised, single oral administration study

Intervention

A single test day during which participants will orally ingest a single microdose of 100 µg 1 µm [14C]-labelled PS-MP. Prior to and following ingestion of the labelled PS-MP, biological samples (i.e. blood, urine, faeces) will be collected at regular intervals, throughout the 5-day study period. Participants will spend the first 24h in the clinical laboratory, after which they are allowed to spend the remainder of the 5-day study period at home but with daily visits to the laboratory for blood sampling and home collection of urine and faeces.

Study burden and risks

The drawing of blood by venepuncture and cannula carries a small risk of local hematoma. The proposed single oral dose of 100 µg PS-MP is below the threshold of toxicological concern for less-lifetime exposure suggested by the ICH M7 guideline and considered safe for volunteers. Moreover, the admitted single dose is in the range of the estimated daily exposure to environmental microplastics of humans and thus the added risk is negligible. The test product will contain a micro tracer amount of 1 µm [14C]-labelled PS-MP (not more than (NMT 15 kBq, 405 nCi), so the volunteers will be exposed to ionising radiation. However, the effective dose was calculated to be 0.011 mSv, which is within risk category I of the ICRP (1992). For comparison, the present study will provide a lower dose of radiation than the ordinary background radiation in the Netherlands (i.e. 2.5 mSv/year), and a lower level to that which one would be exposed to during an airflight to Indonesia (approximately 0.09 mSv).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Healthy males and females using contraception during and for 3 months after the study.
• Aged from 18-65 years at the time of signing informed consent
• 18.5 < BMI < 25 kg·m2
• Must be willing and able to communicate and participate in the whole study
• Must have regular bowel movements (i.e. average stool production of >=1 and <=3 stools per day)

Exclusion criteria

• Diabetes (Type 1, Type 2, or genetic form of diabetes)
• Any diagnosed cardiovascular (heart) disease or high blood pressure (>=140

mmHg systolic and/or >=90 mmHg diastolic)
• History of clinically significant cardiovascular, renal, hepatic, chronic respiratory or gastro-intestinal disease, immunodeficiency, endocrine, neurological or psychiatric disorders
• Known severe kidney problems
• Subjects who have regular gastrointestinal complaints including abdominal pain, stomach upsets and borborygmi, known or suspected irritable bowel syndrome, or functional constipation
• Recent or chronic history of diarrhoea
• Known anaemia
• Known impaired liver function
• A personal or family history of thrombosis (clots), epilepsy, seizures, or schizophrenia.
• Chronic use of any prescribed or over the counter pharmaceuticals (excluding oral contraceptives and contraceptive devices)
• History of any drug or alcohol abuse in the past two years
• A confirmed positive alcohol breath test at screening or admission
• Any known food allergies or intolerances to the 14 major food allergens (celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, molluscs, mustard, tree nuts, peanuts, sesame seeds, soybeans, sulphur dioxide and sulphites) or history of a malabsorption syndrome including coeliac disease
• Currently taking part in other scientific research
• Having received a product with 14C in the past 12 months
• Pregnant or breastfeeding
• Subjects who have taken antibiotics within the 60 days prior to the adaptation period.
• Unable to give consent
• Employed or undertaking a thesis or internship at the department of Human and Animal Physiology

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	11-03-2025
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL88025.028.25