Pilot study into the quantitative relationship of mycotoxins and their biomarkers in paired 24-hour duplicate diets and 24-hour urine samples

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Establishment of a quantitative relationship between 24-hour urinary excretion and 24-hour dietary intake of deoxynivalenol and zearalenone. This pilot study is done to obtain more detailed information needed verify suitability of protocols and…

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

Summary

ID

NL-OMON46621

Source
ToetsingOnline

Brief title
Paired duplicate diet * urine analysis (pilot)

Condition

- Other condition

Synonym
not applicable

Health condition

geen aandoening als zodanig, betreft blootstellingsonderzoek in kader voedselveiligheid

Research involving

Human

Sponsors and support

Primary sponsor: RIKILT
Source(s) of monetary or material Support: Ministerie LNV / NVWA (WOT)

Intervention

Keyword: duplicate diet, food safety, human biomonitoring, urine

Outcome measures

Primary outcome

- 24-hour intake of deoxynivalenol and zearalenone through duplicate diets;

- 24-hour urinary excretion of biomarkers of exposure of these mycotoxins;

- first insight into the existence of a quantitative relationship between

24-hour dietary intake and 24-hour urinary excretion

- insight into the suitability of proposed protocols and methods for the

establishment of quantitative relationships between 24-hour intake of

mycotoxins and 24-hour urinary excretion of their biomarkers

Secondary outcome

Not applicable

Study description

Background summary

Assessment of human exposure to mycotoxins (or in general: contaminants relevant with respect to food safety) is mostly based on food analysis data combined with food consumption data. Human biomonitoring (HBM) is an alternative way to assess exposure. In biomonitoring, biomarkers of exposure are measured in biological materials, often in urine. HBM is more complete in the sense that it also covers unknown or unexpected exposure through food, and exposure through other routes (environmental: dermal absorption, inhalation).

For this reason there is an increased interest in biomonitoring in the EU, also explicitly for chemicals relevant in the frame of food safety.

Urinary biomarker analysis provides information on recent (short term) exposure of a person to mycotoxins. For use of HBM data in risk assessment in food safety, an essential aspect is the possibility to link HBM data with actual expsosure through food. Data to do this are mostly lacking and therefore need to be generated. A simultaneous collection of food consumed on one day and urine excreted on that same day (until the next day's first morning void) will provide such data.

Study objective

Establishment of a quantitative relationship between 24-hour urinary excretion and 24-hour dietary intake of deoxynivalenol and zearalenone. This pilot study is done to obtain more detailed information needed verify suitability of protocols and methods, and to develop the protocol for a subsequent main study.

Study design

Cross-sectional observational study. Participants will be recruited from the general population in the Wageningen area between 18-65 years of age, aiming at equal distributions with respect to sex and age. Participants are asked to collect duplicate diet samples on one day, and a 24-hour urine sample of that same day, and to fill in a questionnaire, a food diary and a urine registration form. The duplicate diets will be analysed for deoxynivalenol and zearalenone (incl. conjugates) and the urine for the corresponding biomarkers. Sample material will be stored for future analysis for other food toxicants.

Study burden and risks

Participants are asked to fill out questionnaires and forms, to collect duplicate portions of all food items consumed during one day, and to collect one 24-hour urine sample on that same day. There are no risks associated with participation due to its observatory nature.

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 subjects (self-reported), age from 18 to 65 years at the time of recruitment

Exclusion criteria

At the time of sampling:
The subject should not be using any prescribed medication
Women should not be menstruating

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL64614.081.18