Assessment of excretion kinetics of urinary biomarkers after a single oral dose of zearalenone in healthy adults

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1) describe the urinary excretion kinetics of ZEN biomarkers; 2a) determine duration of urine sampling for ZEN biomonitoring studies; 2b) describe interindividual differences in formation of *-zearalenol (*-ZEL) and *-zearalenol (*-ZEL) from ZEN in...

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

Summary

ID

NL-OMON49818

Source
ToetsingOnline

Brief title
Urinary excretion zearalenone biomarkers

Condition

- Other condition

Synonym
study of the adverse effects of chemical substances on living organisms, toxicology

Health condition

toxicology

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Food Safety Research
Source(s) of monetary or material Support: Ministry LNV;NVWA (WOT)

Intervention

Keyword: food safety, human biomonitoring, mycotoxins, urine

Outcome measures

Primary outcome

concentrations of ZEN biomarkers (ZEN, *-ZEL, and *-ZEL, measured after

enzymatic deconjugation) excreted in urine over ~72h after ingestion of a

single dose of ZEN.

Secondary outcome

Not applicable.

Study description

Background summary

Assessment of human exposure to chemical substances relevant with respect to food safety is generally based on food analysis data combined with food consumption data. This can, however, give an incomplete picture of exposure, and human biomonitoring is considered an alternative, more complete way to assess dietary exposure. To use human biomonitoring data in risk assessment for food safety, a quantitative relationship between ingested toxicants and excreted biomarkers needs to be established. Particularly for the mycotoxin zearalenone (ZEN), for which excretion takes significantly longer than 12h due to enterohepatic circulation, sufficient knowledge on the urinary excretion kinetics of its biomarkers is lacking.

Study objective

1) describe the urinary excretion kinetics of ZEN biomarkers; 2a) determine duration of urine sampling for ZEN biomonitoring studies; 2b) describe interindividual differences in formation of *-zearalenol (*-ZEL) and *-

zearalenol (*-ZEL) from ZEN in humans.

Study design

observational research without invasive measuring

Intervention

0.1875 *g/kg b.w. of ZEN (i.e. 75% of the tolerable daily intake) as oral bolus in water.

Study burden and risks

Subjects are required to fill out two short questionnaires, visit the campus of Wageningen University and Research and ingest the intervention product, avoid corn and food products containing corn and high amounts of bran for 5 days, keep a food diary for 5 days, and collect urine for 3 days and once on one morning, and fill in a urine collection diary. The avoidance of corn and products containing corn and high amounts of bran is considered to not cause any risks to the subjects as these are considered to not be a significant food staple in the target population, do not contain essential nutrients unique to it, and plenty of alternatives are available to replace those food items in the diet. Risks associated with the intervention are considered to be negligible as the dose is below the tolerable daily intake (i.e. the amount which can be consumed over a lifetime without presenting an appreciable risk to health).

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), aged 18-65 years.

Exclusion criteria

* Subjects with a BMI of 18.5 kg/m2 and below, or 30 kg/m2 and above.
* Subjects using prescribed medication during the duration of the study.
* Pregnant women or women intending to become pregnant during the duration of the study.
* Breastfeeding women.
* Women menstruating at the anticipated days of sample collection.
* Intestinal, liver, biliary, or kidney disease, ileostomy, chronic diarrhea, chronic constipation, celiac disease
* Occupation: working in or frequently visiting (>2d/week) grain silos or flour factories.
* Working at WFSR.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2020
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2020
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	NL72908.081.20