Determination of the optimal biomarkers in urine and hair after oral and dermal pesticide exposure in order to quantify the pesticide exposure*

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Verification of the metabolic pathways and identification of suitable biomarkers of exposure following oral and dermal exposure for each of the selected pesticides in humans.

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

Summary

ID

NL-OMON43439

Source
ToetsingOnline

Brief title
Determination of biomarkers after pesticide exposure

Condition

- Other condition

Synonym
Niet van toepassing

Health condition

aandoeningen zijn geen onderdeel van deze studie. Doel is namelijk het bepalen van humane biomarkers in urine en haar.

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Human Volunteer Study, Pesticide Metabolism, Pesticides exposure, Urine biomonitoring

Outcome measures

Primary outcome

Concentration of parent compound(s) and/or its metabolite(s) in urine and hair

after oral and dermal exposure, including relative metabolite conversion

factors and recovery percentages. In addition, the excretion patterns of

parents/metabolites in urine over the first 48 hours after administration will

be determined.

Secondary outcome

Not applicable

Study description

Background summary

Pesticides are applied in the vicinity of homes and it is unknown what the residents* exposure is. The exposure will be measured by urinary biomonitoring in the *Onderzoek Bestrijdingsmiddelen en Omwonenden* study. To interpret the urinary biomonitoring data, information on human metabolism of the substances is needed. Difficulties may arise when using animal data and therefore a controlled human volunteer study is the best way to interpret biomonitoring data. Benefits of using human volunteers for studying the metabolism at low doses far outweigh the minimal risks involved.

Study objective

Verification of the metabolic pathways and identification of suitable biomarkers of exposure following oral and dermal exposure for each of the selected pesticides in humans.

Study design

Cross-over human volunteer study

Intervention

Each volunteer will be exposed orally and dermally to one of the selected compounds.

Study burden and risks

The maximum quantity of exposure per session will not exceed the acceptable daily intake (ADI) for that pesticide. ADI values established by the EFSA are deemed to be safe for daily exposure over a lifetime. Adverse effects and health risk are therefore not expected. Participants have to visit the research laboratory two times. One session will be dedicated to oral administration and the other session involves dermal administration. After administration, participants have to collect urine over the following 48 hours. The first 8 hours following administration will be spent in an office workplace at the research institute. Participants will also be asked to complete a questionnaire about their personal characteristics, life style and pesticide use. To get a detailed overview of the food intake, volunteers will be asked to complete a 48 h diary.

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

- Good general health i.e. no use of prescribed medication (except oral contraceptives);
- Age between 18 and 65 years;
- BMI between 20 and 25;
- Alcohol consumption less than two standard glasses a day;
- Caucasian (to minimize genetic differences);

Exclusion criteria

- Pregnancy or willing to become pregnant during the study;
- Skin disorders, e.g. atopic eczema, psoriasis, or other chronic skin diseases that causes hyperkeratosis;
- Skin abnormalities on the non-dominant forearm, e.g. scars and injuries;
- Smoking;
- Direct contact or working with pesticides;

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2016
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56428.091.16