Residents and Pesticides

Published: 05-11-2015
Last updated: 10-08-2024

Objective: The primary objective of the study is to determine the personal exposure levels to pesticides of residents living near agricultural land. The secondary objectives of the study are to evaluate the concentrations of pesticides in the...

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

Summary

ID

NL-OMON45814

Source
ToetsingOnline

Brief title
Residents and Pesticides

Condition

- Other condition

Synonym
Exposure to pesticides

Health condition

none

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: National Institute for Public Health and the Environment (RIVM) commissioned by the Ministry of LNV

Intervention

Keyword: exposure assessment, personal exposure, Pesticides

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameters are the

concentration of pesticides or their metabolites in urine samples.

Secondary outcome

The secondary study parameters are the concentration of pesticides in the

outdoor and indoor environment of residents living close to agricultural land

with intensive use of pesticides.

Study description

Background summary

Rationale: The application of pesticides in the vicinity of homes has raised concerns regarding health risks from local residents. Current authorisation procedures of pesticides do not include a separate (independent) assessment of risks for residents, except for residents living near greenhouses. The safety of residents is assumed to be covered by authorisation procedures that apply to operators, workers and bystanders. However, it is not clear if this assumption is valid, given that residents living in the close proximity to agricultural fields where pesticides are used intensively, if exposed at all, are likely exposed to much lower levels. This is due to (secondary) drift, and evaporation of pesticides from nearby agricultural land and possible accumulation of concentrations in the home environment. This may lead to a much longer duration of exposure than only during the period of application. These authorisation procedures also do not take populations with a higher vulnerability into account, such as the unborn, small children or the elderly. The Health Council of the Netherlands recently concluded that there is very limited knowledge about the actual exposure to pesticides of residents in the Netherlands. To close this gap in knowledge, the Dutch government has commissioned the National Institute for Public Health and the Environment (RIVM) to coordinate an exposure assessment study with the objective of *acquiring data on the (potential) exposure of residents in agricultural areas with intensive use of

pesticides*.

Study objective

Objective: The primary objective of the study is to determine the personal exposure levels to pesticides of residents living near agricultural land. The secondary objectives of the study are to evaluate the concentrations of pesticides in the environment of residents living near agricultural land and study the exposure sources and routes contributing to personal and environmental pesticide exposures.

Study design

Study design: This is an observational study without invasive procedures. We will perform an exposure survey in 200 households with at least two eligible participants per household (preferably at least one adult and one child), at locations in close vicinity to treated agricultural land (<500m). Participants will be asked to provide repeated spot urine samples on two occasions (one seven-day period) during the spray season and on one occasion (two-day period) during the off-season. They will be asked to wear a wristband during these periods to measure exposure to pestiides passively. Outdoor as well as indoor concentrations of pesticides in air and on surfaces (dust) will be measured to study the contribution of the different routes of personal exposure. Additional factors that may impact personal pesticide exposure levels, such as diet and activity patterns (the activities people do when they are out of their homes) will be assessed by means of a questionnaire and diaries.
The study is split into two phases: A first project phase (2015-2018) in which only flower bulb-related pesticide exposure has been assessed in a little under 100 households, and a second phase (2024-2026), again with 100 households, in which also pesticides used on fruit will be investigated.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Burden: All subjects will provide repeated urine samples (first morning voids, during one period of 7 consecutive days, and once during 2 consecutive days) and fill in questionnaires and diaries. In addition, inside as well as outside of their homes, air samples and surface samples (dust) will be collected.
We will include children of all age groups (0-6 and 7-17 years), as children have different activity profiles that likely impact exposure levels.
Risks: This is an observational study not involving risks for participants.
Benefit: The study has no direct benefit to the participants. The study will deliver relevant insight into exposure levels as such, as well as into the factors that impact exposure levels in residents in general. This will in turn contribute to future evaluation of potential risks from the exposure to

pesticides in residents. Finally, the study will also contribute to a better understanding of how to reduce exposure to pesticides of residents.

Contacts

Public
Universiteit Utrecht

Yalelaan 2
Utrecht 3584 CM
NL
Scientific
Universiteit Utrecht

Yalelaan 2
Utrecht 3584 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

To be eligible to participate in this study, a subject must have his/her primary place of residence at one of a pre-selected location (i.e., within 500m of a treated agricultural field).

Exclusion criteria

- Inability to complete the administered questionnaires or communicate with the study assistant, e.g. due to insufficient knowledge of the Dutch language or cognitive impairment.
- Doctor diagnosed kidney or liver disease.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2016
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-11-2015
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	23-02-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-09-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-02-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-06-2024
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	NL54727.041.15