Sustainable Plant Protection Transition: a Global Health Approach (SPRINT)

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In agriculture, plant protection products are used to optimize the yield and prevent diseases. Some pesticides can harm agricultural crops, farm animals, the environment and the health of farmers, residents and consumers. The available data on the...

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

Summary

ID

NL-OMON50994

Source
ToetsingOnline

Brief title
SPRINT

Condition

- Other condition

Synonym
Not applicable

Health condition

Niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

Intervention

Keyword: exposure, health, plant protection products, risk assessment

Outcome measures

Primary outcome

The following biomarkers will be studied in all study participants:

1. In blood:

a. blood cell counts

b. general inflammatory/immunologic status: hsCRP, IL-1β, IL-2, IL-4, IL-5,

IL-6, IL-8, IL-10, IL-13 and TNF-α

c. ROS-biomarkers: GSH/GSSG

2. In urine: PPP components and their metabolites, urinary electrolytes,

creatinine, and urinary proteins (OBS)

3. In stool: microbiome analysis

4. In nasal swaps: microbiome analysis

Secondary outcome

Secondary study outcomes in blood:

a. Sister chromatid exchanges (SCE),

b. Reticulocyte and lymphocyte micronuclei (MN),

c. Comets

d. Other inflammatory markers: SAA, VCAM-1 and ICAM-1

e. Neurotoxicity biomarkers: AChE, BChE, GFAP

f. Kidney function: creatinine,

g. Thyroid: fT4, T3, TSH

h. Liver function: ALT, AST, GGT and protein electrophoresis

i. Reproductive: DHEAS, FSH, GGT, LH, s-DHEA, SHBG, testosterone, estradiol,

progesterone and cortisol

j. Untargeted exposome analysis (exogenous)

k. Untargeted metabolome analysis (endogenous)

Secondary study outcomes in urine

a. KID1, NAG

Study description

Background summary

During their daily life, people are exposed to residues of pesticides that are mainly absorbed from food. Farmers (and their families) and residents who live near cropland where plant protection products are applied may have increased exposure. Agricultural policy in the European Union is aimed at reducing the use of plant protection agents. In order to underpin policy, research is needed into the way in which data are collected. The European Commission has therefore awarded a subsidy to a consortium of 29 research institutes from 15 European countries. A large-scale study will be carried out in 2021-2025 to improve data collection methods and calculation models. It is expected that this research will contribute to a careful consideration of all the interests involved in accelerating the sustainability of agriculture with regard to the use of plant protection products.

Study objective

In agriculture, plant protection products are used to optimize the yield and prevent diseases. Some pesticides can harm agricultural crops, farm animals, the environment and the health of farmers, residents and consumers. The available data on the risks and effects of the use of plant protection products are currently incomplete. There is therefore a need for an integrated approach

to collect this missing data. The present research provides for this. This research thus contributes to an acceleration of an already started process of making agriculture more sustainable with regard to the use of plant protection products.

Study design

A harmonised monitoring plan is used to assess plant protection product (PPP) distribution and related to health status, using appropriate and standardised methods to ensure comparability between the different CSS across Europe and South America. A total of 10 CSS communities, covering the diversity of Europe*s landscapes and main farming systems. One additional CSS was selected in Argentina, the main exporter of soy for animal feed in Europe. PPP and metabolites will be selected based on information provided by authorities and farmers. This selection may vary from one CSS to the other.

Study burden and risks

The burden for the participants is estimated to be negligible and consist of the following:
* Collection of morning urine void;
* Collection of stool using a stool collection kit
* Blood collection by vena puncture (single time 5 tubes);
* Wearing a wrist band (7 days);
* Participating in an interview related to collect contextual information such as age, sex, smoking, alcohol use, height and weight (to calculate body mass index); information on lifestyle and some questions related to health status (chronic disease, medication use, chronic infections).
* Keeping a diary with registration of contextual information such as activities, observation of pesticide-related events (e.g. smells), time spent indoor/outdoor/away from home, dietary habits, times of urine collection, etc.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 21N
Nijmegen 6525 HE
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 21N

Nijmegen 6525 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 y or higher age on the day of recruitment
Males and females

Exclusion criteria

Individuals are not able to speak and/or read Dutch will be excluded

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2021
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	01-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-11-2021
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	NL76296.091.20