PARC Healthcare Survey

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To introduce human biomonitoring as a novel approach to study both exposure and as early indicators of effects related to the use of chemicals in hospital-based healthcare. This is expected to increase awareness and better understanding of how work...

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

Summary

ID

NL-OMON56764

Source
ToetsingOnline

Brief title
PARC Healthcare Survey

Condition

- Other condition

Synonym
risk of cancer and reproductive and developmental toxicity

Health condition

Risico op kanker en reproductietoxiciteit en aangeboren afwijkingen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: EU

Intervention

Keyword: cytotoxics, hand disinfection products, human biomonitoring, inhalation anesthetics

Outcome measures

Primary outcome

Cytotoxics (urinary metabolite)

* Cisplatrinum (urinary total platinum)

* Carboplatinum (urinary total platinum)

* Cyclophosphamide

* 5-Fluoruracel (urinary alpha-fluoro-beta-alanine, FBAL)

* Iphosphamide

* Methotrexate

* Doxorubicin

* Gemcitabine

* Docetaxel

* Etoposide

* Paclitaxel

* Cytarabine

Inhalation anaesthetics in end-exhaled air and urine (urinary metabolite)

* Desflurane

* Isofluorane

* Nitrous oxide

* Sevofluorane (trifluoroacetate, hexafluoro-isopropanol)

Disinfection in end-exhaled air (urinary metabolite)

* Ethanol

* Isopropyl alcohol (acetone)

Secondary outcome

In addition to aforementioned exposure biomarkers the following additional

parameters will be studied:

* Micronucleated peripheral blood lymphocyte (PBL-MN)

* Micronucleated reticulocyte (RET-MN)

* Micronucleated Buccal cells (B-MN)

* Comets

* Blood cell counts

* Interleukines, IFN-gamma and TNF-alpha

Study description

Background summary

Workers involved in hospital-based healthcare work with hazardous chemicals. These exposures may result in uptake and potential health effects. Exposure surveillance is required for health risk management and prevention of occupational disease. Human biomonitoring by measurement of specific biomarkers in body fluids is an effective method of exposure surveillance and prevention.

Study objective

To introduce human biomonitoring as a novel approach to study both exposure and as early indicators of effects related to the use of chemicals in hospital-based healthcare. This is expected to increase awareness and better understanding of how work practices contribute to internal exposure to chemicals and how these practices can be further improved to reduce the uptake

of these chemicals.

Study design

Cross sectional survey in nine countries

Study burden and risks

The burden for the participants consists of:
* collection of pre-shift and post shift urine samples;
* collection of blood by vena puncture;
* collection of hand wipes;
* carrying air sampling equipment during work hours;
* participating in an interview to collect contextual information (e.g. on lifestyle and work-related factor);
* participating in a daily interview regarding the tasks performed during the shift.

The risk of participation is considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- 18 y or higher age on the day of recruitment
- Employment in a healthcare or animal research facility
- Access to occupational healthcare provided by a certified service provider
- Exposure to one of the following substance groups during at least two shifts per week: cytotoxics, inhalation anesthetics or hand disinfection products

Exclusion criteria

- Persons who (at the time of the study) have a household member or who care for a patient receiving treatment with cytotoxics (at home or in hospital outpatient clinic)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	72
Type:	Anticipated

Ethics review

Approved WMO Date:	27-05-2024
Application type:	First submission
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	NL86107.091.24