Pilot study concerning urine sampling techniques for biomonitoring in non-toilet trained children

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

Summary

ID

NL-OMON42030

Source
ToetsingOnline

Brief title
Urine sampling techniques in young children

Condition

- Other condition

Synonym
NVT

Health condition

geen aandoeningen, namelijk urine verzamelen tbv biomonitoring

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomonitoring, Collection, Infant, Urine

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameter is the success rate

of each urine collection method. The success rate for one method is defined as

the number of valid samples collected and applicable for analysis.

Secondary outcome

The secondary study parameters are the least burdensome collection method and

the amount of urine collected.

Study description

Background summary

The application of pesticides in the vicinity of homes has raised public concern regarding potential adverse health effects to people living close to the agricultural land where these pesticides are applied. Residents are particularly concerned about their child*s health and cancer. Many epidemiological studies revealed associations between exposure to pesticides and the occurrence of health effects such as reduced fertility, several forms of cancer, especially leukaemia*s, and disorders of the central nervous system (CNS). These findings were particularly uniform for leukaemia in the children of farmers and Parkinson*s disease. The Dutch government has approved an exposure study with the objective of *acquiring data on the potential exposure of residents in agricultural areas where pesticides are used intensively*.
The Health Council reported that there should be a special focus on very young children, because of strong associations between pesticide exposure and childhood leukaemia, and young children are developing and maturating their CNS, immune system and endocrine system from their birth up to their puberty.

Infants and children likely differ from adults in their exposure to environmental chemicals as well as their susceptibility to chemicals, because of various factors such as biometry, behaviour, diet and physiology, which will result in higher exposures (per kilogram body weight) compared to adults and older children. Furthermore, movement patterns of young children have a strong effect on their exposure, and it would not be expected that the exposure of potty-trained children is similar to that of infants. Examples of aberrant behaviour of young children include playing on agricultural fields and grass fields shortly after spraying, putting (soiled) hands and objects in their mouth and crawling. In conclusion, there is a need to develop an appropriate method to acquire pesticide exposure data, particularly for young children (Gezondheidsraad, 2014).
The present protocol describes a pre-study to select a suitable urine collection method for this (main) study where the exposure to pesticides will be evaluated in residents, including young children.

Study objective

The main objective of this study is to evaluate which urine collection method for non-toilet trained children is most suitable for exposure measurement to pesticides with respect tothe burden and convenience, including ease of use, for infants and their parents of each urine collection method. The secondary objectives include the evaluation of whether there is a learning effect and determination of the success rate of each method.

Study design

Study design: This pilot study is designed as a randomized cross-over trial with repeated measurements.

Study burden and risks

Parents will be asked to collect urine of their child on twelve days in total and each selected urine collection method will be used three times. A diary should be kept on each day of urine collection. The risks in this research are negligible since all urine collection methods are non-invasive. In addition, the risk of adverse skin effects and allergic reactions is expected to be negligible as there are no indications in previous studies that such effect would occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Parents with children wearing a diaper
Infant body weight > 2500 g

Exclusion criteria

A bladder infection or other illness or unwellness of the infant at the start of the study. Pre-existing skin problems diagnosed by a medical doctor at the start of the study such as diaper dermatitis or eczema. Hypersensivity to disposable gloves, although latex-free gloves will be provided. Children with a history of an allergic reaction to adhesive tapes.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2015
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	NL51952.091.14