Long term biomonitoring and risk assessment of decabromodiphenylether (DBDE) in humans

Published: 10-10-2006
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- Validation of the distribution of DBDE in human blood - Screening of 4 different European countries on DBDE in human blood - to collect human blood samples over a period of ten years from 80 subjects over a 10 year period to establish a long term...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30004

Source
ToetsingOnline

Brief title
DBDE study

Condition

- Other condition

Synonym
nvt

Health condition

endocrine disruption

Research involving
Human

Sponsors and support

Primary sponsor: Bromine Science and Environment Forum
Source(s) of monetary or material Support: Europese Broomindustrie

Intervention

Keyword: biomonitoring, DBDE, exposure, risk assessment

Outcome measures

Primary outcome

DecaDBE in human blood

Secondary outcome

none

Study description

Background summary

There is lack of reliable data on the levels of DBDE in humans. DBDE is used in plastic materials and in textiles. It is not known whether humans are mainly exposed to DBDE through this route or via the food chain. The bromine industry is reducing the use of DBDE and therefore it is interesting to establish the long term trend in DBDE levels in human blood

Study objective

- Validation of the distribution of DBDE in human blood
- Screening of 4 different European countries on DBDE in human blood
- to collect human blood samples over a period of ten years from 80 subjects over a 10 year period to establish a long term trend
- to investigate effect of lifestyle and environment on DBDE concentrations in blood
- to perform a human risk assessment for DBDE based on the concentrations in blood in this project, combined with results in other ongoing research projects

Study design

Subjects will be visited in a convenient place (work area or home) and in each visit they will have to complete a short questionnaire and 80mls of their blood

is drawn. After a pilot study in 10 participants, 40 subjects from 4 European countries will complete the questionnaire and donate 80mls of blood. Three to six months after the first visit a second follows, to document personal variation in DBDE levels.
The country that has the highest levels of DBDE will participate in the years 3, 5, 7 and 9. In each of those years a group of 40 new subjects and 40 from the previous study period will participate.

Study burden and risks

Participation consists out of completing a questionnaire and a blood donation, this takes 30 minutes. For each participant this will happen at most 4 times in a 2.5 year period. Participants will be visited in a convenient place, and therefore the burden of participation is small.

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

female 20-40 yr old

Exclusion criteria

occupational exposure to DBDE

Study design

Design

Study type: Observational invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	330
Type:	Anticipated

Ethics review

Not approved

Date:	10-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL13197.041.06