Update of a cohort study on the health effects of occupational exposure to phenoxy herbicides and chlorophenols on cancer mortality

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

Summary

ID

NL-OMON30178

Source
ToetsingOnline

Brief title
Research on health effects of exposure to herbicides

Condition

- Other condition
- Lymphomas Hodgkin's disease

Synonym
cancer, death

Health condition

kanker en mortaliteit

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chlorophenols, chlorophenoxy herbicides, dioxins, epidemiologic cohort study

Outcome measures

Primary outcome

blood serum levels of dioxins, furans and PCBs

Secondary outcome

not of influence

Study description

Background summary

In 1984, the IARC in cooperation with the NIEHS established an International Registry of workers occupationally exposed to chlorophenoxy herbicides, chlorophenols and their contaminants in order to assess the possible carcinogenicity of these compounds in humans. RIVM and IRAS participated in the IARC study with a retrospective cohort comprised of two companies producing several chlorophenoxy herbicides.
Chlorophenoxy herbicides are widely used throughout the world in agriculture as herbicide and as defoliants. Chlorophenoxy herbicides are structurally related to chlorophenols that are used as raw material for the manufacture of phenoxyacid herbicides and in wood preservation. During production chlorophenoxyacids and chlorophenols may be contaminated with PCDDs and PCDFs. The results from the first follow-up were inconclusive, because of the short follow-up period resulting in a small number of cases. The results of the second follow-up of this cohort (only factory A), showed increased risks for cancer mortality, respiratory cancer, NHL and ischemic heart disease. However, number of cases was too small to investigate some specific cancers.

Study objective

In the third follow-up we will include both factory A and B. The mayor strength is the increase in power by addition of approximately 15 years of follow-up. We will investigate the association between exposure and mortality, cancer mortality and some specific cancers (NHL, respiratory cancer). Another main objective is to study the shape of the exposure-response relationship. As minor objective we will construct and/or improve exposure models, as has been done previously. Therefore, 50 ml blood will be collected among all surviving cohort members (both factory A and B) who have been exposed to 2,4,5-T and 2,4,5-TCP in factory A or 2,4-D in factory B. We expect about 400 workers are willing to donate blood. Blood will be collected at home. Blood will be used to measure levels of PCDDs. PCDFs and PCBs in blood serum. Remaining of the blood will be stored and later used to investigate effects of exposure to dioxins on immune parameters, gene expression and T-lymphocyte translocations.

Study design

retrospective cohort

Study burden and risks

50 ml blood will be collected among all surviving cohort members (both factory A and B) who have been exposed to 2,4,5-T and 2,4,5-TCP in factory A or 2,4-D in factory B. We expect no harmfull effects of blood donation for participants.

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

For blood collection, all living subjects from both factory A and B are included.

Exclusion criteria

Participants are excluded from blood collection if they have been diagnosed with cancer (other than non-melanome skin cancer).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2007
Enrollment:	400

Type:	Actual

Ethics review

Approved WMO Date:	13-02-2007
Application type:	First submission
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	NL13491.041.06