# Effects of exposure to environmental chemicals on development during adolescence

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The aim of the study is to determine whether prenatal and current exposure to environmental chemicals is associated with developmental outcome in adolescents. We will investigate whether this exposure is associated with the thyroid hormone...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Lipid metabolism disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON40996

**Source**
ToetsingOnline

**Brief title**
Environmental chemicals and child development

### Condition

- Lipid metabolism disorders
- Mental impairment disorders
- Gonadotrophin and sex hormone changes

**Synonym**
Developmental disorders

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Adolescence, Development, Environmental chemicals, Prenatal exposure

## Outcome measures

### Primary outcome

- serum levels of thyroid hormone parameters;

- neuropsychological development;

- pubertal development (stage of breast-, genital-, pubic hair- and axillar hair development; testicular volume; age at menarche/first ejaculation; serum levels of sex hormones);

- physical examination: height, weight, waist circumference and body fat percentage;

- serum levels of parameters of energy metabolism (fasting glucose, insulin, HbA1C, leptin, adiponectin, triglycerides, total cholesterol, HDL- and LDL-cholesterol).

### Secondary outcome

- serum levels of PCBs, OH-PCBs and PBDEs;

- urine levels of BPA, phthalates and PFCs.

# Study description

### Background summary

Several chemicals used in industry do not disappear after its use, but end up in the environment. Studies done by other groups as well as by our group have shown that exposure to these compounds, also at background levels, interfere with the development of the fetus and newborn infant. The fetus and newborn

infants are more vulnerable to the negative effects of these compounds because of their rapid development of organs. Previous studies mainly studied infants during the first two years of life. In a recent study we showed that the effects of these compounds were still detectable at 5-6 years of age. One potential mechanism by which these compounds have an effect is disruption of hormonal processes. Endocrine disruption might be a persistent phenomenon, influencing thyroid hormone metabolism and psycho-motor development, but also pubertal development and energy metabolism. In the present study, we will during adolescence re-evaluate development of infants included in two cohorts in which prenatal exposure to chemicals has been studied in the newborn period.

## Study objective

The aim of the study is to determine whether prenatal and current exposure to environmental chemicals is associated with developmental outcome in adolescents. We will investigate whether this exposure is associated with the thyroid hormone homeostasis, the neuropsychological status, the pubertal development and energy metabolism in adolescents. A second aim is to determine the current exposure levels of polychlorinated biphenyls (PCBs), hydroxylated PCBs (OH-PCBs) and polybrominated diphenyl ethers (PBDEs) in adolescents, and compare them to known prenatal exposure levels.

## Study design

The design of this study is a prospective, longitudinal and observational cohort study. We will invite 190 adolescents of two existing cohorts to participate in this follow-up study. Blood samples will be taken for measurement of thyroid hormone parameters, sex hormones, energy metabolism parameters and the current PCB, OH-PCB and PBDE levels. Urine samples will be collected for assessment of bisphenol A (BPA), phthalates and polyfluoralkyl chemicals (PFCs). The adolescents will perform tests on cognition, motor skills and fill in a questionairre on pubertal development. Measurements of weight, height, waist circumference and assessment of body fat and pubertal stage will be performed. Parents will be asked to fill in questionnaires on behavior.

## Study burden and risks

For investigating the effects of prenatal and current exposure to environmental chemicals on development during adolescence, we will invite all 190 infants to participate in a follow-up study. We will invite them to come one time to the research site after an overnight fast. During that visit:
- Neuropsychological tests will be performed, which will take 2,5 to 3 hours, including instructions and two short breaks of 10-15 minutes.
- Physical examination, including measurements of blood pressure, weight, length, waist circumference and body fat will be performed. For estimating body fat percentage Bioelectrical Impedance Analysis (BIA) will be used. For

assessment of pubertal development, pubertal assessment according to Tanner stages and measurement of testicular volume in boys will be performed by the examiner. A questionnaire on pubertal development will be filled in by the adolescents. In case of refusal for pubertal assessment by the examiner, the infant will be asked for self-assessment of pubertal stage using realistic colored pictures of sexual maturation status and an orchidometer for boys. The total physical examination will take 30 minutes.
- Parents will be asked to fill in four questionnaires on the behavior of the infant.
- Vena punctures will be performed to obtain blood samples (10 ml) for assessment of thyroid hormone homeostasis parameters, sex hormones, energy metabolism parameters and levels of PCBs, OH-PCBs and PBDEs.
- Morning urine samples will be collected for assessment of levels of BPA, phthalates and PFCs.

The burden and risks for the subjects included in the study are minimal. Risks of the vena puncture can be: excessive bleeding; fainting or feeling light-headed; hematoma or blood accumulating under the skin; infection (a slight risk any time the skin is broken); multiple punctures to locate veins.

Data for this study cannot be obtained in another population, as the intention is to study associations of prenatal levels of environmental chemicals with developmental outcomes during adolescence. The results of this study will give more insight into the prenatal and current exposure to environmental chemicals, and the impact of this exposure on various developmental outcomes in adolescents. Our findings may lead to social-medical consequences including potential intervention strategies.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)

## Inclusion criteria

- member of one of the existing cohorts in which prenatal exposure to environmental chemicals have been measured
- written informed consent from the child and both parents

## Exclusion criteria

No exclusioncriteria

# Study design

## Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 23-04-2014 |

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| Enrollment: | 190 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 19-03-2014 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL47703.042.14 |