Follow-up study of the LINC cohort: Chemical exposures and health of adolescents

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

Summary

ID

NL-OMON57082

Source
ToetsingOnline

Brief title
LINC study: Chemical exposures and health of adolescents

Condition

- Other condition

Synonym
Attention deficit hyperactivity disorder

Health condition

neuropsychological development, pubertal development, cardiometabolic outcomes, and respiratory/allergic-related outcomes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chemical pollutants, Environmental health, Longitudinal cohort study

Outcome measures

Primary outcome

The aim of the follow-up study is to assess the impact of perinatal and childhood exposure to multiple chemicals on the development of LINC children, including multiple endpoints/ health outcome domains: neuropsychological development, pubertal development, cardiometabolic outcomes, and respiratory/allergic-related outcomes.

Secondary outcome

N.v.t.

Study description

Background summary

Throughout our lives we are exposed to a variety of synthetic environmental chemicals present in food, water, medicines, the air we breathe, cosmetics and health care products, shoes, clothing, building materials, food packaging, and other consumer products. These chemicals can potentially interfere with physiological and behavioural development, including disrupting normal functioning of the endocrine system (i.e., endocrine disrupting chemicals). As a result, exposure to chemicals during sensitive developmental stages such as the perinatal and childhood periods, has been linked to a wide range of adverse health outcomes, including cardiometabolic diseases, cancer, fertility problems and neurodevelopmental disorders. However, studies that examine the effects of chemicals prospectively are limited and often focus on specific exposed populations or individual chemical compounds. Therefore, it is crucial to study a broad set of chemical exposures in the general population in order to

characterize health impacts and inform chemical health risk assessments and regulations.

Study objective

This study aims to address knowledge gaps regarding health effects of chemical mixtures in childhood/adolescence and their underlying mechanisms. We aim to conduct a follow-up study with children from the LINC birth cohort. The LINC study is a prospective birth cohort study (METC VUmc number: NL31941.029.10) which recruited pregnant women in 2011-2015 in the areas of Zwolle, Purmerend and Den Helder. The primary objective of the follow-up is to answer the research question *What is the effect of environmental chemicals on the development and health of children?*. We will assess neuropsychological development, pubertal development, cardiometabolic outcomes, and respiratory/allergic-related health outcomes of the children/adolescents in the LINC cohort. The secondary objectives of LINC are to (i) assess exposure patterns over time and during sensitive windows of exposure; and to (ii) study associations between chemical exposures and the gut microbiome and mediating role of the gut microbiome.

Study design

A prospective, non-invasive observational assessment will be carried out in which we will investigate the current exposure levels and developmental outcomes of the children in the LINC cohort in 2024-2026, visiting children when they are around 12-13 years (potential range 11-14 years). During the follow-up, children will undergo anthropometric measurements, provide a morning saliva sample, urine samples and a fecal sample, and the children and their parents or caregivers will complete questionnaires. Children will wear a silicone wristband, a passive wearable sampler, for 1 week. Current chemical exposure levels will be measured in urine samples and the wristband, the microbiome composition will be measured in a fecal sample, and steroid hormone levels will be measured in the saliva sample.

Study burden and risks

Little to no risks are expected for participation in the study. Participants will be asked to fill out questionnaires, and collect 1 saliva sample, 3 urine samples on one day, and 1 fecal sample. The child will wear a silicone wristband for one week. Overall, due to the non-invasive design, we expect this to be a small-to-modest burden. A conceivable but negligible risk is the raised awareness of exposure to chemicals in the daily environment of participants, which can potentially lead to concern and stress. However, we will put the exposures (generally low yet ubiquitous) and health risks (generally low in magnitude) in context in communicating the relevance of the research and results. Lastly, we do not expect that group relatedness will hamper inferences

of the epidemiological studies. Siblings are excluded from the study. The children may exhibit some similarity in exposure, health outcome and covariate profiles compared to the variability present in the Dutch population of children*given that mothers/children were and will be recruited in three cities (Zwolle, Purmerend and Den Helder) in a specific period of time*however, we will use statistical models which account for covariates and relatedness as appropriate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

All mothers and children that participated in LINC at baseline will be eligible for the LINC follow-up.

Exclusion criteria

Nvt

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2024
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-10-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL86175.018.24