The LINC-study: LInking EDCs in maternal Nutrition and Child health

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To relate exposure markers of EDCs to health outcomes in children - in particular obesity and neurobehavioral disorders -, effect biomarkers, and other parameters via multiple regression and multivariate analysis, while taking into account relevant...

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

Summary

ID

NL-OMON41667

Source
ToetsingOnline

Brief title
The LINC-study

Condition

- Other condition
- Developmental disorders NEC

Synonym
obesity, overweight

Health condition

Overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Child health, Endocrine Disrupting Chemicals, Maternal nutrition, Prenatal exposure

Outcome measures

Primary outcome

The main study endpoint are health outcomes in children, in particular obesity and neurobehavioral disorders at the age of 12 and 18 months, and 4 years, in relation to exposure markers of EDCs in cord blood.

Secondary outcome

Secundary parameters include health outcomes such as birth weight, height, waist circumference and head circumference. Furthermore outcomes such as asthma, allergies, neurodevelopment, behaviour, sleep and crying will be taken into account. All mentioned parameters will be related to exposure markers of EDCs in cord blood.

Study description

Background summary

A certain class of chemicals has the ability to mimic hormones, disturbing endocrine pathways. These chemicals are referred to as Endocrine Disrupting Chemicals (EDCs). Animal studies have shown that prenatal exposure to some of these EDCs increases body weight in offspring. EDCs have also been related to the development of behavior disorders. However, prospective studies in humans are lacking. It is hypothesized that increased prenatal exposure to EDCs through nutrition and environmental dust is related to an increased risk of

obesity and neurobehavioral problems later in life.

Study objective

To relate exposure markers of EDCs to health outcomes in children - in particular obesity and neurobehavioral disorders -, effect biomarkers, and other parameters via multiple regression and multivariate analysis, while taking into account relevant confounders and covariates.

Study design

This project is embedded in an European multidisciplinary study in which several cohorts participate, in combination with results obtained from animal studies. The current project is designed as an observational cohort study.

Study burden and risks

The LINC-study is an observational study which is primarily based on data collected by regular health care provided by midwifery clinics, obstetricians and youth health care. Furthermore cord blood, placenta, breast milk, urine, vernix, meconium, saliva, a hand-wipe, mouth-wipe and back-wipe of the child, and a dust and air sample will be collected, questionnaires will be administered and head and waist circumference will be measured in children. Collection of all biological samples is non-invasive, as are the measurement of head and waist circumference and the administration of questionnaires. Some questionnaires will cover sensitive topics, but anonymity is ensured. Therefore no injury is expected.
Only pregnant women will be included, therefore the research group may be regarded as group-related. As pregnancy is a normal, physiological process, it is expected that participants will not consider it a problem to be part of this group.
No compensation will be given to the mother-child pairs or to the midwifery clinics. However the mother-child pairs may benefit from the information collected regarding their health and lifestyle, for example regarding their diets.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Healthy women eligible for participation should be less than twelve weeks pregnant at their first visit
to the midwifery clinic. They should be able to fill out Dutch questionnaires. Incapacitated subjects will not be asked to participate.

Exclusion criteria

Women with pre-eclampsia or twin pregnancies are excluded from further participation. Pre-eclampsia is defined as pregnancy-induced hypertension (1x diastolic pressure > 90 mmHg) in association with proteinuria (>0.3 g/day). Furthermore major congenital anomalies at birth will be reason for exclusion.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2015
Application type:	Amendment
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	NL31941.029.10