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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26040

Source
NTR

Brief title
LINC-study

Health condition

Endocrine Disrupting Chemicals
Prenatal exposure
Prenatale blootstelling
Childhood obesity
Overgewicht op de kinderleeftijd

Sponsors and support

Primary sponsor: VU University Amsterdam

European Union: KBBE-2B-227391
Source(s) of monetary or material Support: VU University Amsterdam

European Union: KBBE-2B-227391

Intervention

Outcome measures

Primary outcome

The main study endpoint is BMI at the age of twelve months in relation to levels of exposure markers of EDCs in cord blood.

Secondary outcome

1. Gestational age;

2. Birth weight;

3. Birth height;

4. Head circumference (at birth, 6 and 12 months);

5. Waist circumference (at birth, 6 and 12 months);

6. Asthma;

7. Allergies;

8. Neurodevelopment;

9. Behaviour, sleep, crying.

Study description

Background summary

Rationale:

Obesity prevalence is still increasing, which reflects the complexity of treatment. Emphasis is shifting towards prevention; however more knowledge is needed on the aetiology of obesity. A certain class of chemicals has the ability to mimic hormones, disturbing endocrine pathways. Animal studies have shown that prenatal exposure to some of these endocrine disrupting chemicals (EDCs) increases body weight in offspring. However, prospective studies in humans are lacking. It is hypothesized that increased prenatal exposure to EDCs is related to an increased risk of obesity later in life.

Objective:

To relate exposure markers of EDCs with effect biomarkers, health outcome data and other parameters via multiple regression and multivariate analysis, while taking into account relevant confounders and covariates.

Study design:

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

Study population:

The cohort (N = 500) will be based on women living in the city of Zwolle. 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.

Main study parameters/endpoints:

The main study endpoint is BMI at the age of twelve months in relation to levels of exposure markers of EDCs in cord blood.

Study procedures:

Data will be primarily obtained from regular health care as it is provided for women and children (midwifery clinics and youth health care). Further data on maternal health topics, demographics, diet and exposure of mother and child will be collected by means of questionnaires and collection and analysis of cord blood.

Analysis:

Exposure variables will be categorized in tertiles and it will be tested whether BMI differs significantly between these tertiles. Stepwise regression will be used to quantify the relation between BMI and exposure. Predefined models will be tested which include important covariates.

Study objective

It is hypothesized that increased prenatal exposure to Endocrine Disrupting Chemicals (EDCs) is related to an increased risk of obesity later in life.

Study design

Birth, six months and twelve months.

Intervention

No intervention is planned as this is an observational study.

Contacts

Public
VU University
De Boelelaan 1085, room T-644
Marijke Cock, de
Amsterdam 1081 HV
The Netherlands
+31 (0)20 5983588
Scientific
VU University
De Boelelaan 1085, room T-644
Marijke Cock, de
Amsterdam 1081 HV
The Netherlands
+31 (0)20 5983588

Eligibility criteria

Inclusion criteria

Women eligible for participation should be living in the area of Zwolle and shoud 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. Preeclampsia 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

Intervention model: Factorial

Allocation: Non controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated): 17-01-2011

Enrollment: 500

Type: Anticipated

Ethics review

Positive opinion
Date: 08-12-2010

Application type: First submission

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
NTR-new	NL2528
NTR-old	NTR2646
Other	METC VUMC : 2010/251
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A