

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

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

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving nog niet gestart                            |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON26040

### Bron

Nationaal Trial Register

### Verkorte titel

LINC-study

### Aandoening

Endocrine Disrupting Chemicals

Prenatal exposure

Prenatale blootstelling

Childhood obesity

Overgewicht op de kindertijd

## Ondersteuning

**Primaire sponsor:** VU University Amsterdam

European Union: KBBE-2B-227391

**Overige ondersteuning:** VU University Amsterdam

European Union: KBBE-2B-227391

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

## **Doel van het onderzoek**

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

## **Onderzoeksopzet**

Birth, six months and twelve months.

## **Onderzoeksproduct en/of interventie**

No intervention is planned as this is an observational study.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Factorieel                                          |
| Toewijzing:      | N.v.t. / één studie arm                             |
| <b>Controle:</b> | N.v.t. / onbekend                                   |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 17-01-2011               |
| Aantal proefpersonen:   | 500                      |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 08-12-2010       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

**Register**

NTR-new

NTR-old

Ander register

ISRCTN

**ID**

NL2528

NTR2646

METC VUMC : 2010/251

ISRCTN wordt niet meer aangevraagd.

## Resultaten

**Samenvatting resultaten**

N/A