The Sophia Pluto Study

Gepubliceerd: 26-06-2019 Laatst bijgewerkt: 18-08-2022

Unfavorable exposures during the early postnatal period change programming of growth and metabolic pathways, thereby deranging infant’s body composition and increasing the risk for later obesity and diabetes type 2

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28413

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Obesity, diabetes type II, cardiovascular diseases

Ondersteuning

Primaire sponsor: Investigator initiated
Overige ondersteuning: Independent research grant by Danone Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prenatal and postnatal growth trajectories and prenatal maternal exposures in association with body composition at ages 1, 3, 6 and 9 months with the modification of infants nutritional intake

Toelichting onderzoek

Achtergrond van het onderzoek

Evidence is rising that low birth weight for gestational age and rapid postnatal catch-up growth are risk factors for the development of obesity and diabetes type 2 in adulthood. It has been demonstrated that the early postnatal period is a critical window for the programming of various pathways in tissues and organs, in which nutrition is an important determinant. Up until now pilot data show that rapid postnatal weight gain during the first 3 months of life might cause accelerated fat accumulation which in turn will track into adulthood, but until now it remained difficult to assess infant body composition properly.

Doel van het onderzoek

Unfavorable exposures during the early postnatal period change programming of growth and metabolic pathways, thereby deranging infant’s body composition and increasing the risk for later obesity and diabetes type 2

Onderzoeksopzet

1, 3, 6, 9, 12, 18 and 24 months

Contactpersonen

Publiek

Erasmus Medical Center - Sophia Childrens Hospital
Kirsten de Fluiter

+31-10-7037174

Wetenschappelijk

Erasmus Medical Center - Sophia Childrens Hospital
Kirsten de Fluiter

+31-10-7037174

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria parents:
- Capability of the parents to comply with study protocol.
- Knowledge of the Dutch language.

Inclusion criteria newborns:
- Healthy and full-term infants (gestational age ≥ 36 weeks).
- Children with a neonatal period without severe asphyxia (defined as a Apgar score <3 after 5 minutes), and no serious disease such as long-term artificial ventilation and oxygen supply, broncho pulmonary dysplasia or other lung disease
- Written informed consent from both parents.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria parents:
- Maternal use of corticosteroids during pregnancy.
- Pregnant women/parents known to have other significant medical condition (including during pregnancy) that might interfere with the study or known to affect intra-uterine growth as per investigator’s clinical judgment.

Exclusion criteria newborns:
- Confirmed intra-uterine infection.
- Infants with chromosomal disorders, known syndromes and serious dismorphic symptoms suggestive for a (yet unknown) syndrome.
- Any endocrine or metabolic disorder such as diabetes mellitus, diabetes insipidus, hypothyroidism, or inborn errors of metabolism.
- Infants known to have current or previous illnesses/conditions or intervention which could interfere with the study, such as certain medication (e.g. cortical steroids) or major surgery, as per investigator’s clinical judgement.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	26-06-2019
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	ID
NTR-new	NL7833
Ander register	METC Erasmus Medical Center : MEC-2012-164

Resultaten