Postnatal determinants of metabolic health during the critical window for later obesity

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Primary Objective: Prenatal and postnatal growth trajectories and prenatal maternale exposures, type of feeding, appetite regulating hormones and (epi)genetic factors in association with body composition at ages 1,3, 6 and 9 months and 1 year, 18...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON54742

Source
ToetsingOnline

Brief title
Sophia Pluto Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Danone Research,Research grant van

Danone Research;Stichting Kind&Groei

Intervention

Keyword: body composition, growth, nutrition, obesity

Outcome measures

Primary outcome

The main study parameters are body composition, anthropometric measurements and

metabolic health parameters in serum(e.g. serum lipids, satiety hormones),

saliva (satiety hormones) and stool.

Secondary outcome

Not applicable

Study description

Background summary

Preliminary data suggests 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.
We hypothesize that unfavorable exposures during the early postnatal period change programming of growth and metabolic pathways, thereby deranging infant*s body composition, thereby increasing the risk for later obesity and diabetes type 2.

Study objective

Primary Objective: Prenatal and postnatal growth trajectories and prenatal maternale exposures, type of feeding, appetite regulating hormones and (epi)genetic factors in association with body composition at ages 1,3, 6 and 9 months and 1 year, 18 months, 2 years an during the follow-up study at the age

of 3, 4, 5, 8, 10 and 12 years.

Secondary Objective: Infant*s fat mass accumulation in association with metabolic biomarkers and health parameters, e.g. serum lipids, satiety hormones, metabolic biomarkers and body composition, at the age of 2 years.

The most important goal of this study is to deliver more information about healthy growth, for example to make new feeding guidelines, to prevent obesity.

Study design

Observational follow-up study of a birth cohort

Study burden and risks

Subjects will be included at birth, or within 2 weeks there after, in Erasmus MC / Sophia and will visit the Erasmus MC / Sophia at 1, 3, 6, 9 months and 1 year, 18 months and 2 year.
In this period we will collect 6 blood samples, The total amount of blood drawn will be limited because of special kits. With this kits a couple of drops of blood is needed to measure a lot of hormones. Blood collection will be conducted by trained staff.
At all visits, measurements such as anthropometrics and body composition will be performed. Body composition will be measured using the PEA POD, a validated, non-invasive, safe device. At 6 and 9 months body composition will be also measured by Dual energy X-ray absorptiometry (DXA) scan, which gives very low radiation exposure (approximately 0,0002 msV). Body composition and growth measurements are safe and non-invasive.

During the FU-study, we will use the same priniple of air-displacement plethysmography by BOD POD to investigate body composition in children of 3, 4, 5, 8, 10 and 12 years of age as well as DXA scans for comparison between these two methods. Furthermore, the circadian rhythm will be investigated by an activity tracker watch. Also stress levels will be measured by using hair cortisol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Healthy and full-term infants (gestational age >=37)
- 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.Inclusion criteria follow-up Sophia Pluto Study:
- participation in the Sophia Pluto Study during the first two years of life, even if one or more visit(s) were not completed
- written informed consent from both parentsegeven

Exclusion criteria

- 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.
- Incapability of the parents to comply with study protocol
-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.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2013
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	07-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	16-09-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-04-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	04-03-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL39625.078.12