

The Sophia Pluto Study

No registrations found.

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

Summary

ID

NL-OMON28413

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Obesity, diabetes type II, cardiovascular diseases

Sponsors and support

Primary sponsor: Investigator initiated

Source(s) of monetary or material Support: Independent research grant by Danone Nutricia Research

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Infant's fat mass accumulation in association with metabolic biomarkers and health parameters at the age of 3, 6, 9 months and 1 year, 18 months and 2 years, e.g. serum lipids, satiety hormones, metabolic biomarkers and body composition

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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 dysmorphic 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 non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2012
Enrollment:	1000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion	
Date:	26-06-2019
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	NL7833
Other	METC Erasmus Medical Center : MEC-2012-164

Study results