Postnatal modulation of body composition in preterm infants by human growth factors and hormones in relation to various nutrient compositions.

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The primary objectives of this study is to study the endocrine regulation of growth in preterm infants.Secondary objectives are to study the influence of the endocrine regulation and early nutritional intake on neurodevelopmental outcome, bone...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47744

Source
ToetsingOnline

Brief title
NUTRIE study

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders

Synonym
cardiovascular diseases/heart disease, risk factors for diabetes mellitus/diabetes

Health condition

hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Nutricia,Nutricia Nederland

Intervention

Keyword: Body composition, Growth, Insulin-like growth factor I, Preterm infants

Outcome measures

Primary outcome

The main study parameters are anthropometry (height, weight and body

proportions), body composition and growth-related endocrine parameters.

Secondary outcome

Psychomotor development, bone mineralization, lipid status and blood pressure

Study description

Background summary

Preterm infants are almost universally faced with postnatal growth restriction. Preterm birth, as well as postnatal growth restriction, is associated with impaired neurodevelopmental outcome. Furthermore preterm infants are prone to develop risk factors for the onset of the metabolic syndrome. Postnatal growth patterns, e.g. catch-up growth with rapid weight gain, have been associated with an increased risk for the development of risk factors for the metabolic syndrome. By limiting postnatal growth restriction early nutritional interventions could be a key in improving long-term outcomes of preterm infants. Indeed it has been shown that nutritional interventions can influence neurodevelopment and the onset of risk factors for the metabolic syndrome. Insulin-like growth factor I (IGF-I) is one of the key factors in the endocrine regulation of growth. After birth IGF-I levels quickly drop as the placental supply is suddenly disrupted, to then slowly be restored in preterm infants. We hypothesize that IGF I has to reach a certain threshold before it can effectively influence growth, which might explain the need for a high-energy and high-nutrient diet in the early postnatal period. On the other hand, we

hypothesize that less energy- and nutrient-enrichment is required once IGF-I passes the threshold concentration. At this level the maximum growth rate is expected to be potentiated by IGF-I, reducing the need for extra nutrients and potentially leading to increased fat deposition if diet enrichment is continued. Nonetheless, currently there is no full understanding of the endocrine regulation of growth in preterm infants.

Study objective

The primary objectives of this study is to study the endocrine regulation of growth in preterm infants.
Secondary objectives are to study the influence of the endocrine regulation and early nutritional intake on neurodevelopmental outcome, bone mineralization, lipid profile and blood pressure in preterm infants.

Study design

Cohort study

Intervention

Infants will be randomized to either preterm follow-up formula or standard care at a postmenstrual age of 32-33 weeks.

Study burden and risks

During hospitalisation infants will be subjected to weekly blood draws and anthropometric measurements. Since these preterm infants will be admitted to the Neonatal Intensive Care Unit (NICU)blood draws for research purposes will be combined with blood sampling necessary for clinical care. Infants will be followed up at the outpatient department at term age and 3, 6, 12 and 24 months corrected age for continued anthropometric measurements, body composition and bone mineralization measurements, blood pressure registration, neuropsychologic assessment and a total of 2 blood draws. The burden of the intervention is expected to be minimal and is anticipated to improve long-term outcomes compared to standard care. Due to the nature of the study it is not feasible to conduct the research in another group than preterm infants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Written and informed consent from either the parents or the legal guardians who at least have professional working proficiency of the Dutch, English or French language.
2. Gestational age of 24 to 32 weeks.
3. Arterial catheter in situ.;In order to be eligible for cord blood analysis, a subject must meet all of the following criteria:
1. Gestational age of 24 to 42 weeks
2. Written and informed consent from either the parents or the legal guardians who at least have professional working proficiency of the Dutch, English or French language.

Exclusion criteria

A substantial congenital anomaly based on a chromosomal or syndromal disorder with a known effect on growth and body composition.

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):	29-09-2015
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	5311
CCMO	NL50196.029.14