Postdischarge nutrition in infants born <32 weeks gestation and/or <1500 grams birth weight: relation with growth, body composition and metabolic health at 7 years (STEP 2)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON39311

Source
ToetsingOnline

Brief title
STEP 2

Condition

- Hypothalamus and pituitary gland disorders

Synonym
hypertension, metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support:
FrieslandCampina;Leeuwarden;Nederland,Hero BV, Breda, Nederland

Intervention

Keyword: body composition, metabolic health, nutrition, preterm

Outcome measures

Primary outcome

The main study parameters are anthropometry (height, weight, head circumference

and body proportions), body composition and salt sensitivity of blood pressure

at 7 years of age.

Secondary outcome

Secundary study parameters are endocrine factors (IGF-1, cortisol, leptine

o.a.), cholesterol, psychomotore development, cognitieve development and bone

mineralisation.

Study description

Background summary

Early and aggressive feeding protocols in term low birth weight infants leading to increased growth in the first year of life are associated with increased risk of disease later in life, such as diabetes, cardiovascular disease and obesity. Preterm infants already are at risk for adverse metabolic effects, which may be explained by the *fetal origins hypothesis* and the *catch up growth hypothesis*. Insulin resistance and salt sensitivity are suggested to be major factors in the association between prematurity and diseases in later life. In preterm born children and adolescents the tendency to retain salt may become a central mechanism for the development of hypertension and cardiovascular risk and is also important for developmental outcome. Early nutritional interventions, especially low salt intake, may decrease salt sensitivity. Higher protein intake with postdischarge formula between term date

and 6 months corrected age results in more lean mass and less fat mass. It is hypothesized that infants fed postdischarge formula have more lean mass, less fat mass, lower blood pressure, decreased salt sensitivity and higher bone mineralization at 7 years compared to those fed term formula. Infants fed postdischarge formula are hypothesized to be comparable to infants fed human milk at 7 years.

Study objective

The main objective of the study is to evaluate differences in body size, body composition and metabolic health at 7 years between children fed postdischarge formula and term formula. Secondary objectives are differences in bone mineralization and development at 7 years between children fed postdischarge formula, term formula and human milk. Also, differences in body size, composition and metabolic health at 7 years between children fed postdischarge formula and human milk are evaluated.

Study design

This study is an interventional and observational follow up study.

Intervention

A high salt diet is used for 7 days. The extra salt is provided as dietary sodium chloride supplements in a dose of 0.12 gram/kg body weight per day.

Study burden and risks

Subjects will be asked to visit our outpatient clinic twice. Subjects are asked to collect three salivary samples before the first visit. Before resp. the first and second visit a regular diet and high salt diet is used for 7 days and a three day dietary dairy is kept. At both visits blood pressure will be measured and a fasting blood sample is collected for hormonal, renal and cholesterol parameters to evaluate metabolic health. On day 1 and 2 resp. 23.5 and 15.5 ml blood is drawn. Anthropometry, whole body DEXA scan and developmental tests will be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Participants of STEP 1 study. In short, infants born with gestational age 32 weeks or less and/or birth weight 1500 gram or less.

Exclusion criteria

Gastro-intestinal surgery and disease known to influence growth; known presence of growth hormone, IGF-1 or other pituitary hormone deficiencies; cardiac, renal, pulmonary and liver disease; chromosomal and/or genetic syndromes; known presence of rickets, osteopenia or other skeletal disease; severe illness; concurrent therapies with substances known or suspected to be associated with alteration of growth.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-01-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29242
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35113.000.10
OMON	NL-OMON29242