

Postdischarge nutrition in infants born

No registrations found.

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

Summary

ID

NL-OMON29242

Source

NTR

Brief title

STEP2

Health condition

Growth; body composition; metabolic health; blood pressure

Sponsors and support

Primary sponsor: VU University Medical Center Amsterdam

Source(s) of monetary or material Support: FrieslandCampina, Leeuwarden, the Netherlands; Hero BV, Breda, the Netherlands.

Intervention

Outcome measures

Primary outcome

1. Anthropometry;
2. Body composition (lean mass, fat mass).

Secondary outcome

1. Blood pressure;
2. Endocrine parameters (e.g. insulin, glucose, IGF-1, FT4, TSH, cortisol);
3. Salt sensitivity of blood pressure;
4. Lipid status;
5. Neuromotor and cognitive development;
6. Bone mineralization.

Study description

Background summary

Rationale:

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. Insulin resistance and salt sensitivity are suggested to be major factors in the association between prematurity and diseases in later life. 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.

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.

Study population:

Subjects to be included are participants of the “Study Towards the Effect of Postdischarge nutrition on growth and body composition of infants born < 32 weeks gestational age and/or < 1500 gram birth weight”. They were fed postdischarge formula, term formula or human milk between term date and 6 months corrected age. All participants of the STEP study included up till 2 years corrected age will be approached for recruitment. Exclusion criteria are gastro-intestinal surgery, chromosomal and genetic syndromes and diseases known to influence growth. Subjects and their parents may withdraw at any time.

Main study parameters/endpoints:

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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 diary 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.

Study objective

Preterm born infants fed protein enriched postdischarge formula have similar catch-up growth for weight, length, and head circumference, but 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. At 7 years, preterm born infants fed postdischarge formula are hypothesized to be comparable to infants fed human milk.

Study design

Day 1 and day 2 (2-4 weeks later).

Intervention

Subjects will follow a regular diet for seven days followed by evaluation of blood pressure at our outpatient clinic. Several weeks later they use a regular diet enriched with 0,12

gram/kg/day salt (high salt diet) for seven days followed by a second evaluation of blood pressure at our outpatient clinic. Subject will be supplied with the amount of salt for seven days and receive strict instructions.

Contacts

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Eligibility criteria

Inclusion criteria

Participants of the “Study Towards the Effect of Postdischarge nutrition on growth and body composition in infants born <32 weeks gestational age and/or <1500 gram birth weight” at 7 years of age.

Exclusion criteria

Subjects with the following criteria will be excluded from the study:

1. Gastro-intestinal surgery and disease known to influence growth (i.e. cystic fibrosis);
2. Known presence of growth hormone, IGF-1, or other pituitary hormone deficiencies;
3. Concurrent therapies with substances known or suspected to be associated with alteration of growth;

4. Cardiac, renal, pulmonary, and liver disease;
5. Chromosomal and/or genetic syndromes (other than Silver-Russel);
6. Known presence of skeletal disease;
7. Severe illness.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2011
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion	
Date:	06-07-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39311
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2831
NTR-old	NTR2972
CCMO	NL35113.000.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39311

Study results

Summary results

N/A