Study Towards the Effects of Post discharge nutrition on growth and body composition of infants born

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26207

Source
NTR

Brief title
STEP

Intervention

Outcome measures

Primary outcome

Growth and body composition (bone density, fat percentage).

Secondary outcome

1. Anemia;

2. bone markers;

3. protein status;

4. metabolism (o.a. glucose, cholesterol, IGF-I);

5. free fatty acids in red blood cells;
6. neurodevelopment.

Study description

Background summary

N/A

Study objective

To study the effects of post dicharge nutrition on the growth, body composition, metabolism and neurodevelopment of premature infants .

To study the effects of catch-up growth on the body composition, metabolism and neurodevelopment of premature infants.

Intervention

Randomization to post discharge or term formula between 0 and 6 months corrected age. Breast milk group as a control group.

All the formula and the breast milk with fortifier are prescribed in a volume of ± 175 ml/kg/day (160-190ml/kg/day).

The infants are seen at the outpatient clinic at 0, 3, 6, 12 and 24 months corrected age. Anthropometry is performed and motorneurodevelopment is tested by a physiotherapist. At 0, 3 and 6 months corrected age a fasting venous blood sample is taken and urine is collected. At 0 and 6 months corrected age the body composition is established with a DEXA scan. Parents keep weekly dairies and telephonic support is offered on a regular bases.

Contacts

Public
VU University Medical Center,
Department of Paediatrics/Neonatology,
P.O. Box 7057, dep 9D11
E.M. Amesz
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4442480

Scientific
VU University Medical Center,
Department of Paediatrics/Neonatology,
P.O. Box 7057, dep 9D11
E.M. Amesz
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4442480

Eligibility criteria

Inclusion criteria

Gestational age <= 32 weeks with a birth weight <= 2000 grams or a birth weight <= 1500 grams and a gestational age <= 34 weeks.
At least one parent or caretaker who speaks Dutch or English.

Exclusion criteria

Conditions that influence the growth like:

1. Severe congenital anomalies;

2. Bronchopulmonary dysplasia defined as an O2 requirement above 25% at 36 weeks gestation, any O2 requirement at 38 weeks gestation or any respiratory support at 40 weeks gestatio';

3. Severe intracerebral haemorrhage or ischaemia diagnosed before inclusion;

4. Gastrointestinal surgery and gastro-intestinal diseases known to influence growth.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2003
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	21-07-2005
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	NL32
NTR-old	NTR55
Other	: N/A
ISRCTN	ISRCTN53695702

Study results

Summary results

Publications: Amesz EA, Schaafsma A, Cranendonk A, Lafeber HN. Optimal growth and lower fat mass in preterm infants fed a protein-enriched postdischarge formula. JPGN 2010;50:200-207.

Brief summary: Feeding nutrient-enriched formula without extra energy after term does not change quantity of growth, but does influence type of weight gain and body composition of preterm infants. Infants fed the nutrient-enriched formula had lower fat mass corrected for body size at six months corrected age than infants fed standard formula or human milk. There were no differences in growth or body size between infants fed postdischarge formula, standard formula, and human milk.