Nutrition in relation to the endocrine regulation of preterm growth

No registrations found.

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

Summary

ID

NL-OMON27985

Source
NTR

Brief title
NUTRIE study

Health condition

Preterm infants
Insulin-like growth factor I
Growth
Body composition

Sponsors and support

Primary sponsor: VU University medical center
Source(s) of monetary or material Support: Nutricia Nederland B.V. : Unrestricted research grant

Intervention

Outcome measures

Primary outcome

1. Growth (height, weight, body proportions and growth pattern)

2. Body composition

3. Growth-related endocrine parameters

Secondary outcome

1. Psychomotor development

2. Bone mineralization

3. Lipid status

4. Blood pressure

Study description

Background summary

In October 2016 the following changes were made:
- An additional reference group (n=100) of infants born between 32 and 42 weeks of gestation has been added for the analysis of endocrine parameters in cord blood;

In January 2017 the following changes were made:
- The intervention is stopped, because of insufficient number of formula-fed infants;
- The number of participants with a gestational age less than 32 weeks was reduced from 150 to 70.

Study objective

Insulin-like growth factor I (IGF-I) is one of the key factors in the endocrine regulation of growth in preterm infants. 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 threshold concentration before it can effectively influence growth. Furthermore it is expected that less energy- and nutrient-enrichment is required once IGF-I passes the threshold concentration. The maximum growth rate is then 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.

Study design

During hospitalisation infants will be subjected to weekly anthropometric measurements and blood draws once every 2 weeks until a postmenstrual age of 36 weeks. 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.

In October 2016 the following changes were made:
- A food frequency questionnaire of maternal nutrition during pregnancy was added for participants with a gestational age lower than 32 weeks;
- The frequency of anthropometric measurements between 30 and 36 weeks postmenstrual age was reduced to once every 2 weeks instead of weekly.

Intervention

Preterm infants (born < 32 weeks) fed limited energy- and nutrient-enriched preterm follow-up formula at a postmenstrual age of 32-33 weeks will be compared to preterm infants fed according to the standard regime. Formula fed infants will be randomized to either a full energy- and nutrient-enriched preterm starter formula until a postmenstrual age of 32-33 weeks (intervention group) or until term age (control group). In both groups the preterm starter formula will be followed-up by a limited energy- and nutrient-enriched preterm follow-up formula until 6 months corrected age. From 6 months onwards both the intervention as well as the control group will be fed regular follow-up term formula. The study will also include a breast fed reference group which will be fed fortified breast milk until term age, according to current practice.

In January 2017 the intervention is stopped, because of insufficient number of formula-fed infants;

Contacts

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Eligibility criteria

Inclusion criteria

In October 2016 the following changes were made:
- An additional reference group (n=100) of infants born between 32 and 42 weeks of gestation has been added for the analysis of endocrine parameters in cord blood;

In January 2017 the following changes were made:
- The intervention is stopped, because of insufficient number of formula-fed infants;
- The number of participants with a gestational age less than 32 weeks was reduced from 150 to 70.

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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2015
Enrollment:	170
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-07-2015
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	NL5171
NTR-old	NTR5311
Other	NL50196.029.14 : ABR Dossiernummer

Study results