ProtEUs

No registrations found.

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

Summary

ID

NL-OMON28714

Source
Nationaal Trial Register

Brief title
ProtEUs

Health condition

Infant formula, Kunstvoeding
Protein intake, eiwitinname
Body Composition, lichaamssamenstelling

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: The European Union's Seventh Framework Programme (FP7/2007-2013), project EarlyNutrition under grant agreement n°[289346]

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to investigate equivalence of weight gain from randomisation until 17 weeks of age in infants receiving the formula with an optimized amino acid composition and a lower total protein content compared to infants receiving the control

product: a formula with a standard amino acid composition and protein content.

Secondary outcome

Body composition:

- Body fat percentage

- Fat-free mass (FFM)

- Fat mass (FM)

- Fat-free mass index (FFMI)

- Fat mass index (FMI)

- Skinfold thickness

Plasma concentrations of:

- Total IGF-1

- Glucose

- Insulin

- IGFBP1, IGFBP2, IGFBP3

- Leptin

- Urea

Metabolomics:

- Amino acid profile

- Polar lipids

Anthropometric measurements:

- Head circumference

- Length

- Waist circumference

- Mid-arm circumference

Study description

Background summary

The prevalence of childhood obesity is increasing rapidly, its prevention is becoming a public health priority. Several
observational studies have shown an association between early nutrition and the risk of developing obesity later in life.

Formula-fed infants are more likely to become overweight compared with breast-fed infants. An important reason for this
appears to be the higher protein content of formula. An infant formula with improved protein quality and a lower protein
quantity may be of benefit to infants.

Objective of the study:

To assess the effect of an infant formula with an optimized amino acid composition and a lower total protein content
during the first four months of life on infant growth.
Study design:

Multicenter, double blind, randomized controlled trial.

Study population:

Healthy term infants.

Intervention (if applicable):

The intervention group (group A) will receive an infant formula with an optimized amino acid composition and reduced
protein content (test product) and the control group (group B) will receive infant formula with a standard amino acid
composition until the 26th week of age (control product). The intervention will start before the 45th day of life. Data on theprimary and secondary endpoints will be collected until 26 weeks of age.
A reference group with breast-fed infants (group C) will undergo the same measurements at the same time points.

Primary study parameters/outcome of the study:
Infant weight gain from inclusion to the age of 17 weeks.

Secundary study parameters/outcome of the study (if applicable):

- Body composition

- Blood concentrations of total IGF-1, glucose, insulin, IGFBP1, IGFBP2, IGFBP3, leptin, amino acid profile, urea,
metabolomics.

- Anthropometric measurements: length, waist circumference, head circumference, mid-arm circumference.

- Composition of fecal microbiota.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if
applicable):

The infants will visit the hospital 3 times during the study: at baseline and at 4 and 6 months of age. Each visit will take
about an hour. A blood sample will be taken at the age of 4 months. The amount of blood that will be taken is minimal (3
ml). During the intervention period, nutritional intake will be measured by a food questionnaire. For the determination of
body composition, the infants will visit the hospital 3 times during the intervention period.

There are no reasons to expect any risks from consumption of a formula partially based on free amino acids. There are
various reasons to hypothesize that infant formula with an optimized amino acid profile and a lower protein level exhibits
beneficial effects on growth, body composition and metabolic diseases in later life. Therefore it is possible that infants
fed with this formula may benefit from participation in the study by lower risk of overweight later in life.

Countries of recruitment: The Netherlands and Germany

Study objective

We hypothesize that an infant formula with an optimized amino acid composition and a lower protein content during the first 26 weeks of age is safe and results in comparable growth to standard formula fed infants at 17 weeks of age.

Furthermore we hypothesize that infant formula with an optimized amino acid profile and a lower protein level exhibits beneficial effects on weight gain, body composition and metabolic diseases in later life.

Study design

The infants will visit the hospital 3 times during the study: at baseline and at 4 and 6 months of age. During the whole intervention period, nutritional intake will be measured by a food questionnaire.

Intervention

Formula-fed infants will be randomized into group A (test product) or group B (control product). Infants in group A will receive an infant formula with an optimized amino acid composition and infants in group B will receive an infant formula based on the standard amino acid composition. The study intervention ends at 26 weeks of age.

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Eligibility criteria

Inclusion criteria

- Born at term (born >37 weeks of gestation)

- Birth weight between p3 and p97 (WHO growth curves birth to 6 months of age)

- Age ≤ 45 days after birth

- Formula-fed (administration of one feed/gift human milk per day is allowed) OR human milk-fed (administration of one feed/gift infant formula per day is allowed.

- Written informed consent of both parents or legal guardians

Exclusion criteria

- Multiple birth

- Infants known to have current or previous illnesses/conditions or intervention which could interfere with the study (growth), as per investigator's clinical judgement

- Infants with known congenital diseases or malformations which could interfere with the study (e.g. gastrointestinal malformations, congenital immunodeficiency), as per investigator's clinical judgement

- Infants who need to be fed with a special diet other than a standard cow's milk-based infant formula

- Infants with any history of or current participation in any other study involving investigational or marketed products.

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):	01-10-2014
Enrollment:	291
Type:	Actual

Ethics review

Positive opinion
Date: 03-10-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41548
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4677
NTR-old	NTR4829
CCMO	NL47744.029.14
OMON	NL-OMON41548

Study results

Summary results
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