ProtEUs: Effects of an infant formula with an optimized amino acid composition on growth and body composition in infants

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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. Amendment follow-up study: To assess the long term effect of the intake of an...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41548

Source
ToetsingOnline

Brief title
ProtEUs

Condition

- Other condition

Synonym
Growth and overweight

Health condition

Groei, overgewicht en obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europse Unie,Nutricia

Intervention

Keyword: Body composition, Growth, Infant formula, Protein

Outcome measures

Primary outcome

Infant weight gain from inclusion to the age of 17 weeks.

Amendment follow-up study: BMI at the age of 6 years.

Secondary outcome

- 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.

Amendment follow-up study:

- Body composition

- Blood concentrations of total IGF-1, glucose, insulin, IGFBP1, IGFBP2,

IGFBP3, leptin, amino acid profile, urea, metabolomics.

- Anthropometric measurements: weight, length, waist circumference, head

circumference, mid-arm circumference.

- Composition of fecal microbiota.

- Blood pressure

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.

Amendment follow-up study: The quantity and quality of protein intake during the first months of life seems to have a programming effects on the risk of obesity and associated diseases. The intake of an infant formula with an optimized amino acid composition and a lower total protein content leads to a lower BMI compared to infants fed with standard formula. We hypothesize that the intake of an infant formula with a lower protein content leads to a more beneficial body composition (e.g. lower body fat percentage) and metabolic profile compared to the intake of standard formula.

Study objective

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.

Amendment follow-up study: To assess the long term effect of the intake of an infant formula with an optimized amino acid composition and a lower total protein content during the first months of life on growth.

Study design

Multicenter, double blind, randomized controlled trial.

Intervention

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 the primary 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.

Amendment follow-up study: no additional intervention

Study burden and risks

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.

Amendment follow-up study: The infants will visit the hospital 3 times during the follow-up study: at the age of 1, 2 and 6 years of age. Each visit will take about an hour. A blood sample will be taken at every visit. The amount of blood that will be taken is minimal (3 ml). During the follow-up period, nutritional intake will be measured by a food diary. For the determination of body composition, the infants will visit the hospital 3 times during the follow-up period. A feaces sample will be taken at the age of 1,2 and 6 years of age. Blood pressure will be measured at the age of 6 years.
There are no reasons to expect any risks from participating in the follow-up study. There will be no intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Healthy term infants
- Age <= 45 days after birth

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-10-2014
Enrollment:	146
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 28714
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47744.029.14