Mercurius 5 years follow-up study

No registrations found.

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

Summary

ID

NL-OMON28614

Source
Nationaal Trial Register

Brief title
Mercurius 5 year FU

Health condition

Healthy infants

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research

Intervention

Outcome measures

Primary outcome

Key outcome: Body Mass Index (BMI) at 3, 4, and 5 years of age

Secondary outcome

- Prevalence of overweight and obesity at 3, 4, and 5 years of age

- Sum of skin fold thicknesses at 3, 4, and 5 years of age

- Percentage total body fat (derived from skinfolds)

- Head- and waist- circumference at 3, 4, and 5 years of age

Study description

Background summary

The present study is a follow up study of the original Mercurius study (NTR3683) at the age of 3-5 years. The main objective of this study is to gain insight into the possible long-term effects, up to 5 years of age, on growth and body composition development in subjects who have received the test product compared to subjects who have received the control product in the first 4 months of age and in comparison to the breastfed reference group. Study visits will take place at 3, 4 and 5 years of age. A phone call will take place at 3.5 and 4.5 years of age.

Study objective

The infant formula containing a new fat blend, consumed in the first 4 months of life, will have a positive effect on the growth trajectory in toddlerhood up to 5 years of age.

Study design

Visit at 3, 4 and 5 years of age. Phone call at 3.5 and 4.5 years of age

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

- Subjects that participated in the original Mercurius study (NTR3683) up to visit 5 (approx. 4 months of age) are eligible for this follow up study.

- Written Informed Consent

Exclusion criteria

- Investigator's uncertainty about the willingness or ability of the child and parents to comply with the protocol requirements.

- Subjects that were recruited by investigators who decided not to participate in the 5 year follow up study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	230
Type:	Anticipated

Ethics review

Positive opinion Date:	21-12-2015
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	NL5421
NTR-old	NTR5538
Other	: EPI1.C.C Nutricia Research

Study results