

# Mercurius 5 years follow-up study

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	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