MERCURIUS 5 years Follow-Up: a follow-up study of a randomised, controlled, double-blind study to investigate the effects of a new infant formula given in the first 4 months of life on growth and body composition up to 5 years of age

Published: 11-09-2015
Last updated: 19-04-2024

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 of an infant formula containing a new fat blend given in the first 4 months of life

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42552

Source
ToetsingOnline

Brief title
MERCURIUS 5 years Follow-Up study

Condition

- Other condition

Synonym
Effects on growth

Health condition

effect op groei

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Effect on growth, Follow-up study, Healthy infants, New infant formula, up to 5 years of age

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.

Study objective

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 of an

infant formula containing a new fat blend given in the first 4 months of life

Study design

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.

Intervention

nvt

Study burden and risks

In the present study no product intervention is given. In addition, no invasive assessments are performed. Therefore, no risks are expected from participation in this study.

Contacts

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Nutricia Research

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Participation in the Mercurius study (NTR3683) up to visit 5 (4 months of age)
- Written informed consent from parent(s) or legally acceptable representative(s)

Exclusion criteria

- The Investigator's uncertainty about the willingness or ability of the child and parents to comply with the protocol requirements
- Subjects of the Mercurius study (NTR3683) whose Principle Investigator chose not participate in the Mercurius 5 years Follow-Up study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-09-2015
Application type:	First submission

Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	08-08-2016
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Not approved Date:	31-10-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	30-05-2018
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
CCMO	NL54365.072.15