'Study on infant Adiposity development To Understand the Role of early life Nutrition - the Sophia Saturn Study'

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Primary Objective:To investigate change in fat mass index between 6 and 12 months of age in infants receiving Nuturis® formula feeding versus standard formula feeding during the first 6 months of life.Secondary Objectives:- To investigate change in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON54727

Source
ToetsingOnline

Brief title
The Sophia Saturn Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym
Obesity, Overweight

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Independent research grant van Nutricia

Research,Nutricia

Intervention

Keyword: Body Composition, Growth, Nutrition, Obesity

Outcome measures

Primary outcome

The main study parameter is change in fat mass index from 6 to 12 months of age.

Secondary outcome

Secondary, associations with other body composition parameters (fat mass, lean mass, fat mass percentage, subcutaneous and visceral fat mass), anthropometric measurements (e.g. weight, length, weight-for-length, BMI and skinfolds SD), metabolic biomarkers (e.g. serum lipids, satiety hormones), eating behavior and neurocognitive development will be investigated.

Study description

Background summary

Breastfeeding is considered as the gold standard for infant nutrition. Human milk is the optimal source of nutrients for the growth of infants in the first months of life. It provides the best nutritional components delivered in the most efficient way and it conveys the best immunologic protection from a healthy mother to her child. This is established by the optimal composition of the macronutrients and micronutrients. Breastfeeding results in short term positive nutritive and developmental effects, but also in long term benefits. Among the short term beneficial effects are the development of the immune system and the colonization and establishment of the gut microbiota, whereas in the long term breastfeeding has been shown to protect for the prevalence of overweight or obesity.
Unfortunately, breastfeeding is not always possible or desirable and then infant formula is the best alternative solution. The scientific community has been striving to better understand the properties and composition of human

milk, the fate of its ingested nutrients, the regulation of digestion, and as a result is learning which nutrient quantities and formats are preferable and available for absorption and deposition into tissues and leading to optimal growth and development. This acquired knowledge is continuously being incorporated into the further improvement of infant milk formulas.
An innovative infant formula concept has been developed in which, compared to current standard formula, the lipid quality and structure have been improved, resulting in lipid droplets closer to those present in human milk (Nuturis®).
In two randomized, controlled, double-blind, multi-country trials, Nuturis® was demonstrated to be well-tolerated, supporting adequate growth and being safe for use in healthy term infants. Growth patterns in Nuturis®-fed infants were more balanced and closer to the breastfed reference. However, the effect of Nuturis® on infant body composition development was not investigated. Other studies show a positive effect of breastfeeding on neurocognitive function/intelligence compard to formula feeding. In the extension study, at age 3, 4 and 5 years, we investigate if Nuturis feeding also shows a positive effect on neurocognitive function/intelligence.

Study objective

Primary Objective:
To investigate change in fat mass index between 6 and 12 months of age in infants receiving Nuturis® formula feeding versus standard formula feeding during the first 6 months of life.

Secondary Objectives:
- To investigate change in fat mass index over time in infants receiving Nuturis® formula feeding or standard formula feeding during the first 6 months of life, compared to a breastfed reference group.
To investigate effects on other body composition parameters (e.g. total fat mass, fat mass percentage, subcutaneous and visceral fat mass) and anthropometric measurements (e.g. weight, length, weight-for-length, BMI and skinfolds SD) during the first 5 years of life.
- To explore associations of growth and body composition development with maternal characteristics (e.g. pre-pregnancy BMI, smoking, excess gestational weight gain), with metabolic biomarkers (e.g. serum lipids, satiety hormones) and with eating behavior of infants receiving Nuturis® formula feeding versus standard formula feeding and compared to a breastfed reference group.

Study design

A randomized, placebo-controlled, double-blind study to investigate the effect of Nuturis® versus standard formula feeding on the longitudinal change in fat mass index, when parents decided to start formula feeding in infants within 6 weeks after birth.

Intervention

Intervention: Nuturis formula feeding, start within 6 weeks after birth until 6 months of age
Control: Standard formula feeding, start within 6 weeks after birth until 6 months of age

Study burden and risks

Subject will be included within 6 weeks after birth and will visit the Sophia Children's Hospital at randomization, 3, 6, 9, 12, 18 and 24 months and at 3,4 and 5 years. In this period we will collect 9 blood samples. The total amount of blood will be limited due to the use of special kits so that a few drops of blood is enough. Blood collection will be conducted by trained staff.
At all visits, measurements such as anthropometrics and body composition will be performed. Body composition will be measured by PEA POD, a validated, non-invasive, safe device. From 6 months onwards, body composition will be measured by DXA-scan, which gives very low radiation exposure (approximately 0.0002 mSv). Both body composition and growth measurements are safe and non-invasive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

- Participation in the Sophia Pluto Study (MEC-2012-164)
- Parents have decided to start formula feeding
- Healthy, full-term infants (gestational age >= 37 weeks)
- Children with a neonatal period without severe asphyxia (defined as an Apgar score < 3 after 5 minutes) and no serious disease such as long-term artificial ventilation and oxygen supply, broncho pulmonary dysplasia or other lung disease
- Written informed consent from both parents

Exclusion criteria

- Maternal use of corticosteroids during pregnancy
- Pregnant women/parents known to have other significant medical condition (including during pregnancy) that might interfere with the study or know to affect intra-uterine growth as per investigator's clinical judgement
- Incapability of the parents to comply with the study protocol
- Confirmed intra-uterine infection
- Infants with chromosomal disorders, known syndromes and serious dismorphic symptoms suggestive for a (yet unknown) syndrome
- Any endocrine or metabolic disorder such as diabetes mellitus, diabetes insipidus, hypothyroidism or inborn errors of metabolism
- Infants known to have current or previous illnesses/conditions or intervention which could interfere with the study, such as certain medication (e.g. cortical steroids) or major surgery, as per investigator's clinical judgement

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2019
Enrollment:	234
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-07-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL64048.078.18