A randomised, controlled, double-blind trial to investigate the effects of a new infant formula on growth, tolerance and safety in healthy term infants.

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The primary objective of this study is to investigate equivalence of weight gain from randomisation until the age of 17 weeks in infants receiving the test product compared to infants receiving the control product. Secondary objectives of this study…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39783

Source
ToetsingOnline

Brief title
Mercurius

Condition

- Other condition

Synonym
effects on growth

Health condition

effect op de groei van zuigelingen

Research involving

Human

Sponsors and support

Primary sponsor: Nutricia Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Nutricia Research - Centre for specialised nutrition

Intervention

Keyword: effect on growth, healthy term infants, new infant formula, Nuturis, tolerance / safety

Outcome measures

Primary outcome

Weight gain in grams per day from randomisation until 17 weeks of age [g/day].

Secondary outcome

Gain from randomisation until 17 weeks of age of: - Recumbent length [mm/day] - Head circumference [mm/day] - Mid-upper arm circumference [mm/day] - Skin folds (subscapular, triceps) [mm/day]. Total weight gain in gram from randomization until 12 months of age [g/day]. Gain from randomization until 12 months of age of: Recumbent length [mm/day] - Head circumference [mm/day] - Mid-upper arm circumference [mm/day] - Skin folds (subscapular, triceps) [mm/day]. Sum of skin folld thickness: triceps, biceps, suprilliac, subscapular [mm/day].
Z-scores of anthropometric parameters until 17 weeks and 12 months of age: - Weight-for-age z-scores - Weight-for-length z-scores - Length-for-age z-scores - BMI-for-age z-scores - Head circumference-for-age z-scores - Mid-upper arm circumference-for-age z-scores - Skinfold-for-age z-scores (subscapular, triceps) Number, type and severity of (serious) adverse events Use of medication and nutritional supplements Gastrointestinal tolerance parameters

utnil 17 weeks of age (via a diary) including: - Occurrence and severity of gastrointestinal symptoms (cramps, diaper/nappy rash, regurgitation, and vomiting) - Stool frequency - Stool consistency - Occurrence of diarrhoea and constipation.

Study description

Background summary

Breast-feeding is considered as the gold standard for infant nutrition, as it provides the best nutritional components delivered in the most efficient way and it also conveys the best immunological protection from a healthy mother to her child. However, breast-feeding is not always possible or appropriate due to circumstance and for such cases infant formula is the logical solution. It is known that breast-fed infants have a different growth pattern later in life as compared to formula-fed infants, and this may be related to differences in nutrient composition between human milk and infant formula. The lipid (fat) composition and structure of human milk, in particular, is different from that in infant formula. This study will evaluate the effect of the new infant formula on the infant*s growth, and will also evaluate the intestine complaints or symptoms. In addition, this study will measure the effect of this new infant formula on immune status and gut microbiota.
Sub-study: Infants gain weight faster in early infancy than at any subsequent age, and judging whether weight gain is within normal limits during the first 4 months is part of the safety assessment of infant formula studies. Most infants show a period of weight loss immediately after birth, before this rapid weight gain begins. The majority of infants regain their birth weight within the first 14 days postpartum. To make sure that this period of weight loss immediately after birth and regaining of birth weight is included into the safety assessment, it has been decided to include a minimal fixed number of infants up until 14 days of age at inclusion in the study, in addition to the total number of infants recruited until 35 days of age at inclusion as originally planned. This will allow us to better establish safety of the test product compared to the control product in this sub-population of young infants. The importance of this period is also reflected in the guidelines of some countries, which state that safety studies with infant formula should be done in infants starting formula up until 14 days of age (guidelines of the American Academy of Paediatrics (American Academy of Paediatrics, 1988). Due to the differences in growth rates breastfed infants are significantly leaner then formula-fed infants between 6 and 12 months of aged. In addition to growth, assessment of body composition has shown that the growth differences between 6 and 12 months

of age are likely due to less rapid decrease in adiposity in formula-fed infants compared to breastfed infants. In order to gain insight into the possible long-term effects on growth of the new formula product given up to 17 weeks of age, an optional vist at 12 months of age has been added to the study.

Study objective

The primary objective of this study is to investigate equivalence of weight gain from randomisation until the age of 17 weeks in infants receiving the test product compared to infants receiving the control product. Secondary objectives of this study are: - To investigate equivalence of other growth parameters from randomisation until the age of 17 weeks in infants receiving test product compared to infants receiving the control product - To assess gastrointestinal tolerance and safety from randomisation until the age of 17 weeks in infants receiving the test product compared to infants receiving the control product. To investigate efficacy on weight gain from randomisation until the age of 12 months in infants receiving te test product compared to infants receiving the control product until 17 weeks of age.

Study design

This is a randomised, controlled, double-blind, parallel-group, prospective, multi-country, intervention study.

Intervention

Infants who will be randomised equally to the following groups:
- Test group: receiving test product
- Control group: receiving control product
Infants who are exclusively breastfed and whose mothers are willing to exclusively breastfeed for at least till their infant is 13 weeks of age (and preferably 17 weeks of age) will enter the breastfeeding reference group (not applicable for the sub-study). These infants will not be randomised.

Study burden and risks

There are no special risks for the infants. Potential inconveniences of the study include emotional stress during the voluntary blood drawing procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy term infants (gestational age >= 37 1/7 and <= 42 6/7 weeks) - Age <= 35 days (preferably as soon as possible after birth) - Birth weight within normal range for gestational age and sex (10th to 90th percentile according to local applicable growth charts) - Infants who are exclusively formula fed (mothers who have chosen not to breastfeed or mothers who ended breastfeeding by time of inclusion) or - Infants who are exclusively breastfed and whose mothers are willing to exclusively breastfeed at least till their infant is 13 weeks of age (and preferably till 17 weeks of age).
For the sub-study:
Once 176 infants receiving study product have been included in the main study, inclusion in the sub-study will start. The inclusion criterium **Age <= 35 days (preferably as soon as possible after birth)** will no longer be valid and be replaced by: **Age <= 14 days (preferably as soon as possible after birth)**.

Exclusion criteria

- Infants known to have current or previous illnesses/conditions or intervention which could interfere with the study or its outcome parameters, such as gastrointestinal malformations, congenital metabolic disorders, immune deficiency or major surgery, as per investigator*s

clinical judgement - Infants whose mother is known to suffer from hepatitis B or human immunodeficiency virus (HIV)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2014
Enrollment:	124
Type:	Actual

Ethics review

Approved WMO Date:	07-01-2013
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	14-03-2014
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	NL42715.072.12

Study results

Date completed:	16-12-2014
Results posted:	12-01-2022
Actual enrolment:	121

Summary results
Trial is onging in other countries

First publication
19-02-2020