An exploratory study to evaluate the effect of a new study product on early programming in healthy infants

Published: 17-01-2011
Last updated: 30-04-2024

To compare the new IMF with the control IMF.

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

Summary

ID

NL-OMON34471

Source
ToetsingOnline

Brief title
EAGLE2

Condition

- Other condition

Synonym
digestion and absorption

Health condition

healthy subjects

Research involving
Human

Sponsors and support

Primary sponsor: Danone Vitapole
Source(s) of monetary or material Support: Danone Research BV

Intervention

Keyword: Infant milk formula (IMF)

Outcome measures

Primary outcome

Absorption and digestion of feed components.

Secondary outcome

NA

Study description

Background summary

A study to compare a new infant milk formula (IMF) with a control IMF in healthy infants.

Study objective

To compare the new IMF with the control IMF.

Study design

7 week intervention with the new IMF versus a control IMF.

Intervention

7 week feed with the new IMF or the control IMF

Study burden and risks

2x2 Blood samples are collected via heelprick.

Contacts

Public
Danone Vitapole

Bosrandweg 20
6704 PH Wageningen
NL
Scientific
Danone Vitapole

Bosrandweg 20
6704 PH Wageningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy and full-term infants (gestational age * 37 and * 42 weeks)
Birth weight within the normal range for gestational age and sex (10th to 90th percentiles according to applicable growth charts)
Age * 7 weeks at screening
Body weight appropriate for the individual age and sex at screening (10th to 90th percentiles according to applicable growth charts)
Infants who are fully formula fed or have started the transition from breast- to formula-feeding (indicated by the feeding of at least one bottle of infant formula in the past) and are planning to stop breastfeeding voluntarily by infant*s age of 7 weeks
Written informed consent of both parent(s)/legal guardian(s)

Exclusion criteria

Infants not on full formula feeding at the age of 7 weeks (to be answered latest at the age of 8 weeks (visit 2))
Infants with known congenital diseases or malfunctions e.g. gastrointestinal malformations, haemophilia
Current or previous illnesses which could interfere with the study (e.g. prolonged severe diarrhoea, regurgitation)
*Infants with abnormal growth (too slow (< -1SD) or too fast (> +1SD) weight gain) within the 10th to 90th percentiles of applicable weight-for-age charts for either boys or girls
Infants at high risk to develop an atopic disease (at least one parent or sibling with manifest atopic symptoms of hay fever, asthma or atopic dermatitis)
Infants needing a special diet other than standard cow*s milk-based infant milk formula
*Infants whose mothers are known to suffer from hepatitis B, human immunodeficiency virus (HIV), high blood-pressure, hyperlipidaemia or diabetes
Infants whose mother was overweight (BMI * 27) prior to pregnancy
Infants with any historical or current participation in any other study involving investigational or marketed products
Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements and instructions

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2011
Enrollment:	28

Type:	Actual

Ethics review

Approved WMO Date:	17-01-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-03-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL32379.000.10