Study to investigate the nutritional efficacy and suitability of infant formulae in healthy full-term infants.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21301

Source
NTR

Brief title
Giraffe study

Health condition

Healthy full-term infants

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Weight gain.

Secondary outcome

1. Recumbent length gain;

2. Increase in head circumference.

Study description

Background summary

This study aims to investigate the nutritional efficacy and suitability of two infant formulae with slightly modified composition in healthy full-term infants compared to a currently marketed infant formula primarily on weight gain in the first 16 weeks of life. A follow-up visit will take place at 52 weeks of life. During the intervention period parents will be asked to record gastrointestinal tolerance and formula intake. In a subgroup of infants (on a voluntary basis) a blood sample will be collected at the age of 16 weeks for nutritional status and safety.

Study objective

The investigational formulae are equivalent to the currently marketed control formula with regard to weight gain of healthy full-term infants during first 16 weeks of life.

Study design

Screening, baseline, visits on 4, 8, 12, 16, and 52 weeks.

Intervention

Duration of intervention: 14-16 weeks.

Intervention groups: Two investigational formulae with slightly modified composition.

Control group: the control formula is a currently marketed infant formula.

Contacts

Public
Uppsalalaan 12
Lilian van Tuyl
Utrecht 3584 CT
The Netherlands

+31 (0)30 2095000
Scientific
Uppsalalaan 12
Lilian van Tuyl
Utrecht 3584 CT
The Netherlands
+31 (0)30 2095000

Eligibility criteria

Inclusion criteria

1. Healthy full-term infants (gestational age > 37 and < 42 weeks, birth weight > 2.5 kg);

2. Infants with appropriate birth weight within normal range for gestational age and sex;

3. Infants aged <= 14 days at study entry;

4. Infants who are exclusively formula fed (mothers who have chosen not to breastfeed or mothers who ceased breastfeeding by time of inclusion);

5. Written informed consent from both parents.

Exclusion criteria

1. Infants with birth weight > 4.5 kg;

2. Infants diagnosed with a congenital illness or malformation that could affect normal growth;

3. Infants with significant pre- or postnatal disease;

4. Infants that are already participating in another clinical trial;

5. Infants with cows' milk allergy, soy allergy or lactose intolerance.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	156
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-12-2009
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	NL2011
NTR-old	NTR2128
Other	Nutricia Research : All.3.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A