Exploratory study to investigate the effects of a new infant formula in healthy term infants during the first 6 months of life.

No registrations found.

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

Summary

ID

NL-OMON20946

Source
NTR

Brief title
COMBI Study

Health condition

healthy infants

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research - Centre for Specialised Nutrition
Blédina SA

Intervention

Outcome measures

Primary outcome

1. To investigate the effects on the composition and metabolic activity of the intestinal microbiota (e.g. percentage of bifidobacteria and potential pathogens, pH and short-chain fatty acids) and on the immune status (e.g. SIgA) in healthy term infants during the first 6 months of life of:

A. An IF containing immunologically active ingredient 1 and/or immunologically active ingredient 2 compared to a standard IF;

B. The three investigational formulas compared with each other.

2. To assess intestinal tolerance and safety of an infant formula containing immunologically active ingredient 1 and/or immunologically active ingredient 2;

3. As reference, to assess the composition and metabolic activity of the intestinal microbiota (e.g. percentage of bifidobacteria and potential pathogens, pH and short-chain fatty acids) and on the immune status (e.g. SIgA) in healthy term exclusively breast-fed infants during the first 6 months of life.

Secondary outcome

N/A

Study description

Background summary

The parents are approached in the first 7 days of their infant's life to participate in the study if their infant is eligible. The study consists of 4 visits and 1 follow-up phone call. During each visit the infants are examined and a stool sample is collected. Also diaries are filled in by the parents in-between visits. The duration of the study participation for each infant is 25 to 26 weeks, depending on the age at baseline. Then 2 weeks after the end of the intervention period a follow-up phone call takes place to record the current feeding regime and any (serious) adverse events which might have occurred after visit 4.

Study objective

That the combination of two known immunologically active ingredients can effectively modulate the intestinal microbiota and immune system and thereby might reduce the incidence of allergy and infections.

Study design

Time points of the outcome: The whole study will take around 1 year and 1 month.

1. Visit 1: Screening, randomisation and baseline at 1-7 days of age;

2. Visit 2: 2 months of age;

3. Visit 3: 4 months of age;

4. Visit 4: 6 months of age;

5. Follow-up phone call: 6 months and 2 weeks of age.

Intervention

Duration of intervention: 6 months.

Intervention group 1: Healthy infants receiving a standard cow’s milk-based infant formula containing a combination of two known immunologically active ingredients.

Intervention group 2: Healthy infants receiving a standard cow’s milk-based infant formula containing immunologically active ingredient 1.

Intervention group 3: Healthy infants receiving a standard cow’s milk-based infant formula containing immunologically active ingredient 2.

Control group: Healthy infants receiving a standard cow’s milk-based infant formula with the same composition as the Investigational Formula 1, but without supplementation with active ingredients.

Reference group: Exclusively breast-fed infants.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy term infants (gestational age 37 to 42 weeks);

2. Birth weight within normal range for gestational age and sex (10th to 90th percentile according to applicable growth charts);

3. Age ≤ 7 days at baseline;

4. For infants to be randomised into one of the formula groups: 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);

5. For infants to be recruited into the breast-fed reference group: Infants who are exclusively breast-fed since birth (never received any infant formula) and with the mother's intention to continue exclusive breast-feeding until the infant's age of at least 4 months;

6. Written informed consent from both parents;

7. Parents' willingness and ability to comply with the protocol requirements.

Exclusion criteria

1. Infants whose mothers are known to suffer from hepatitis B, Human Immunodeficiency Virus (HIV) or Group B Streptococcal infection (GBS);

2. Infants whose mothers have taken antibiotics while breast-feeding;

3. Infants having received antibiotics prior to participation in the study;

4. Current or previous illnesses which could interfere with the study (e.g. prolonged severe diarrhoea);

5. Known congenital diseases or malformations which could interfere with the study (gastrointestinal malformations, congenital immunodeficiency);

6. High risk to develop an atopic disease (at least one parent or sibling with manifest atopic symptoms of hay fever, asthma or atopic dermatitis);

7. Need to feed a special diet other than standard cow's milk-based IF;

8. Study pre-feedings which could interfere with the study, e.g. non-cow's milk-based formulas, HA formulas, probiotic formulas.

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):	01-02-2011
Enrollment:	350
Type:	Actual

Ethics review

Positive opinion

Date:	01-02-2011
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	NL2598
NTR-old	NTR2726
Other	Danone Research : CAX.1.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A