A study on the effect of a Growing up milk on the occurrence of infections in toddlers

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27240

Source
NTR

Brief title
GIANT (Growing up milk, Infections and Toddlers)

Health condition

Infections
(Dutch: infecties)

Sponsors and support

Primary sponsor: Danone Research B.V. (formerly known as Numico Research B.V.)
Source(s) of monetary or material Support: Danone Research B.V.

Intervention

Outcome measures

Primary outcome

The number and duration of episodes (in days) of upper respiratory tract infections and/ or gastrointestinal infections based on a combination of subject illness' symptoms reported by

parents.

Secondary outcome

- Parents’ reported symptoms of illness and/ or allergy

- Use of medication

- Visits to a physician

- Illnesses diagnosed by a physician

- Hospitalization

- Daycare absence and parents’ absence of work due to illness of the toddler

- Anthropometrics

- Gastrointestinal tolerance

- Dietary intake (in a subgroup)

Study description

Background summary

In this study the effect of a Growing up milk with added prebiotics and LCPUFA will be compared with the effect of a Growing up milk without prebiotics and LCPUFA on the occurrence of infections in healthy toddlers during a year.

Study objective

It is expected that drinking Growing up milk with added prebiotics and LCPUFA will results in a lower occurrence of infections in healthy toddlers compared to a Growing up milk without prebiotics and LCPUFA.

Study design

Visit 1: Screening

Visit 2: Baseline

Visit 3: Week 2

Visit 4: Week 14

Visit 5: Week 26

Visit 6: Week 38

Visit 7: Week 52

A run-in period between screening and baseline.

Several phone contacts between the visits during the study.

Intervention

Duration intervention: 1 year (+ 4 weeks run-in)

Intervention group: a Growing up milk with added prebiotics and LCPUFA for toddlers.
Control group: a Growing up milk without prebiotics and LCPUFA for toddlers
The study will also include a reference group of toddlers who use cow’s milk.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy subjects between 11 and 29 months of age

2. Attending a daycare centre for at least 2 times per week

3. Expected study product intake of 400 – 750 ml per day

4. Written informed consent from the parents

Exclusion criteria

1. Subjects who were never ill in the last 6 months

2. Atopic dermatitis according to the Hannifin criteria

3. Disorders requiring a special diet

4. Any relevant congenital abnormality, chromosomal disorder or severe disease

5. Pre-existing pathology of severe respiratory or gastrointestinal diseases

6. Diagnosed immunodeficiency disease

7. Current use of anti-regurgitation, anti-reflux or laxative medication

8. Expected inability to adhere to protocol instructions

9. Participation in any other study involving investigational or marketed products concomitantly

10. Currently being breastfed

11. Current use of immunomodulators

12. Current use of prophylactic prescribed antibiotics

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	650
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-09-2008
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	NL1391
NTR-old	NTR1451
CCMO	NL24606.072.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A