

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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27240

Bron

NTR

Verkorte titel

GIANT (Growing up milk, Infections and Toddlers)

Aandoening

Infections
(Dutch: infecties)

Ondersteuning

Primaire sponsor: Danone Research B.V. (formerly known as Numico Research B.V.)

Overige ondersteuning: Danone Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	650
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 22-09-2008

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1391
NTR-old	NTR1451
CCMO	NL24606.072.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A