

Growing up milk with new fat composition and probiotics to target infections in Indonesian toddlers.

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The growing-up milk products with a new fat composition and probiotics are effective to reduce the duration and symptoms of respiratory and gastrointestinal tract infections.

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

Samenvatting

ID

NL-OMON22249

Bron

NTR

Verkorte titel

GIRAFFE

Aandoening

Respiratory tract infections, gastrointestinal tract infections

Ondersteuning

Primaire sponsor: FrieslandCampina Innovation Infant & Toddler Nutrition

Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Duration of respiratory tract and gastrointestinal tract infection episode.

Toelichting onderzoek

Achtergrond van het onderzoek

The leading causes of death in children under 5 years of age are respiratory tract infections and diarrhea. Young children, and especially toddlers, encounter many pathogenic microorganisms including viruses, bacteria and parasites, making it of major importance to target these diseases. There are complex processes underlying gastrointestinal tract and respiratory tract infections. Adequate and high quality nutrition can play a pivotal role in reducing infection risk.

This study investigates the effects of growing up milks containing an optimized fat blend with and without probiotics on 1. duration and incidence of respiratory tract and gastrointestinal tract infections, 2. gut microflora, mucosal inflammation and rotavirus prevalence, and 3. physical growth. The study will be performed in 300 Indonesian toddlers between 1 and 3 years of age.

Doel van het onderzoek

The growing-up milk products with a new fat composition and probiotics are effective to reduce the duration and symptoms of respiratory and gastrointestinal tract infections.

Onderzoeksopzet

1. Weekly symptom monitoring via questionnaire;
2. Visits at t=0, t=1, t=2, t=3, t=4, t=6, t=8, t=10 and t=12 months;
3. Fecal sample collection at t=0, t=4, t=8 and t=12 months and in case of acute diarrhea.

Onderzoeksproduct en/of interventie

Group 1: Standard Growing up milk;

Group 2: Growing up milk + new fat blend;

Group 3: Growing up milk + new fat blend + probiotic 1;

Group 4: Growing up milk + new fat blend + probiotic 2.

Contactpersonen

Publiek

FrieslandCampina Innovation Infant & Toddler Nutrition

P.O. Box 226
Marjolijn C.E. Bragt - van Wijngaarden
Leeuwarden 8901 MA
The Netherlands
+31 (0)58 2992447

Wetenschappelijk

FrieslandCampina Innovation Infant & Toddler Nutrition

P.O. Box 226
Marjolijn C.E. Bragt - van Wijngaarden
Leeuwarden 8901 MA
The Netherlands
+31 (0)58 2992447

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy Indonesian children;
2. Between 1 and <3 years of age;
3. Non-breastfed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. In sick condition 1 month before the start of the study;
2. Receiving antibiotics treatment 2 weeks before the study starts;
3. Breastfeeding 2 months prior to the start of the intervention period;
4. Consumption of pre-, pro- or synbiotic products at least 2 weeks prior to the intervention;
5. Symptoms of chronic/congenital diseases and disabilities, suspected Tuberculosis by clinical examination, and/or history of allergic diseases;

6. Use of medication that can interfere with the study 2 months before the start, such as strong anti-inflammatory drugs;
7. History of lactose intolerance;
8. History of cow's milk allergy;
9. Siblings of already included children that are living in the same household, except if it is a twin sibling;
10. Participation in another clinical trial at the same time or 2 months prior to the study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	05-07-2012
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	NL3362
NTR-old	NTR3510
Ander register	FrieslandCampina : 0.7-20120126
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A