

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22249

### Source

NTR

### Brief title

GIRAFFE

### Health condition

Respiratory tract infections, gastrointestinal tract infections

## Sponsors and support

**Primary sponsor:** FrieslandCampina Innovation Infant & Toddler Nutrition

**Source(s) of monetary or material Support:** FrieslandCampina

## Intervention

## Outcome measures

### Primary outcome

Duration of respiratory tract and gastrointestinal tract infection episode.

### Secondary outcome

1. Incidence of infection;
2. Severity of infection;
3. Physical growth;
4. Rotavirus prevalence;
5. Gut microflora;
6. Mucosal inflammation.

## Study description

### Background summary

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.

### Study objective

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.

### Study design

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.

### Intervention

Group 1: Standard Growing up milk;

2 - Growing up milk with new fat composition and probiotics to target infections in ... 6-05-2025

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.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

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

### Exclusion criteria

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.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2012
Enrollment:	300
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	05-07-2012

## 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	NL3362
NTR-old	NTR3510
Other	FrieslandCampina : 0.7-20120126
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A