Study to explore the effect of a Growing Up Milk with added synbiotics on the intestinal microbiota of healthy Asian toddlers.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21383

Source
NTR

Brief title
SMILE

Health condition

Healthy toddlers

Sponsors and support

Primary sponsor: Danone Research ¨C Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research ¨C Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Ratio bifidobacteria to total faecal bacteria.

Secondary outcome

1. Ratio of other bacteria groups to total faecal bacteria;

2. Faecal short chain fatty acids;

3. Faecal lactate;

4. Faecal pH;

5. Faecal secretory IgA;

6. Parent's reported symptoms of illness.

Study description

Background summary

The effect of a Growing up milk with added synbiotics will be compared with the effect of a Growing up milk without added synbiotics on the intestinal microbiota of healthy Asian toddlers in a 12-weeks, randomised, double blind controlled intervention study.

Study objective

A positive effect of the investigational product on the intestinal microbiota of healthy Asian toddlers is expected.

Study design

The whole intervention phase will take 12 weeks.

V1: screening (week -1);

V2: baseline (week 0);

Contact 1: week 1;

V3: week 6;

V4: week 12;

Contact 2: week 14.

Intervention

Duration of intervention: 12 weeks;

Intervention group: 65;

Control group: 65.
The intervention group will receive Growing Up Milk with added synbiotics. This is powder-based Growing Up Milk (GUM) with added prebiotics (scGOS/lcFOS), probiotics (B. breve M-16V) and LCPUFA. The control group will receive Growing Up Milk with added LCPUFA, but without the prebiotics.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy Asian subjects between 1 and 3 years of age;

2. Expected study product intake 500 - 650 ml per day;

3. Access to a freezer or a refrigerator with an ice tray for temporary storage of stool samples;

4. Written informed consent from parents.

Exclusion criteria

1. Being breastfed in the 4 weeks before inclusion;

2. Disorders requiring a special diet (such as food intolerance or food allergy or complaints such as reflux, constipation and cramps for which special toddler formula is required);

3. Significant congenital abnormality that will interfere with the study objectives in the opinion of the investigator;

4. Risk factors on infection linked to probiotics, such as cardiac insufficiency and cardiac abnormalities including cardiac malformation, or immunodeficiency;

5. Use of oral/systemic antibiotics or anti-mycotic medication in the 4 weeks preceding the study screening or expected use during the study;

6. Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements;

7. Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study.

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):	01-06-2010
Enrollment:	130

Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL2148
NTR-old	NTR2273
Other	Danone Research : Tod.1.C/F /
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A