Effect of the consumption of a fermented dairy product on constipation in childhood: a multi-centre randomized controlled trial.

No registrations found.

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

Summary

ID

NL-OMON24332

Source
Nationaal Trial Register

Brief title
Nu233

Health condition

Childhood constipation

Sponsors and support

Primary sponsor: Danone Research
Source(s) of monetary or material Support: Danone Research

Intervention

Outcome measures

Primary outcome

The primary endpoint is the stool frequency change from baseline to 3 weeks of product consumption.

Secondary outcome

Stool frequency over 3 weeks and at week 1 and 2 of product consumption.

- Stool consistency over 3 weeks and per week of product consumption.

- Frequency of episodes of faecal incontinence over 3 weeks and per week of product consumption.

- Pain during defecation over 3 weeks and per week of product consumption.

- Digestive symptoms: abdominal pain and flatulence over 3 weeks and per week of product consumption.

- Adverse effects: nausea, diarrhoea and bad taste over 3 weeks and per week of product consumption.

- Intake of Bisacodyl over 3 weeks and per week of product consumption.

- Rate of success defined as 3 or more bowel movements per week and less than 1 faecal incontinence episode in 2 weeks over the last 2 weeks of product consumption

- Rate of responders defined as a subject who reports a stool frequency ¡Ý 3 on the last week of product consumption

Study description

Background summary

-

Study objective

The study objective is to show that Bifidobacterium animalis is effective in increasing defecation frequency after 3 weeks of product consumption in children with functional constipation.

Study design

The total duration of the study is approximately 5 weeks for each subject. Each patient will attend 3 clinic appointments: Inclusion visit V1 (baseline),

randomisation visit (V2) and clinical evaluation at weeks 3 (V3).

Intervention

Fermented dairy product Activia® (125-g pot) containing Bifidobacterium animalis DN-173 010, 1.2 1010 colony forming units (cfu) per pot and a yoghurt symbiosis Lactobacillus bulgaricus and Streptocccus thermophilus (1,2.109 cfu/pot).

Contacts

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Eligibility criteria

Inclusion criteria

1. Children (boys and girls) aged from 3 to 16 years

2. Children with a diagnosis of functional constipation according to Rome III criteria (Rasquin et al.):

- subjects must present defecation frequency < 3 / week

- subjects must present 1 or more of the following criteria:

- faecal incontinence > 1 / week

- large amount of stools which clog the toilet

- painful defecation

- withholding behaviour

- abdominal or rectal faecal impaction upon physical examination

3. Children with a diagnosis of functional constipation according to Rome III criteria fulfilled for the last 2 months

4. Children with usual consumption of dairy products and ready to consume 2 pots per day

5. Children having given written consent to take part in the study (in The Netherlands: children and parents for children above 12 years and only parents for children under 12 years; in Poland: children and parents for children above 16 years and only parents for children under 16 years)

Exclusion criteria

1. Children with a diagnosis of IBS according to Rome III criteria

2. Children treated for constipation less than 2 weeks before intake in the study

3. Children with mental retardation or metabolic disease (hypothyroidism)

4. Children with Hirschsprung¡¯s disease or spinal anomalies or anorectal pathology

5. Children who underwent gastro-intestinal surgery

6. Children with functional non-retentive faecal incontinence

7. Children with lactose intolerance or known allergy to product component (milk protein for example)

8. Children who started a medication with antibiotics in the prior month

9. Children receiving medication influencing gastrointestinal motility (for

examples Cisapride, Motilium, Erythromycin, laxatives, Loperamide)

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2008
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-12-2008
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	NL1501
NTR-old	NTR1571
Other	: NU233
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A