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

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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.

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

Samenvatting

ID

NL-OMON24332

Bron
Nationaal Trial Register

Verkorte titel
Nu233

Aandoening

Childhood constipation

Ondersteuning

Primaire sponsor: Danone Research
Overige ondersteuning: Danone Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

-

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-12-2008
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	NL1501
NTR-old	NTR1571
Ander register	: NU233
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A