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

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To determine the clinical effect and tolerance of BA in children with functional constipation aged 3-16 years.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON30819

Source
ToetsingOnline

Brief title
Bifidobacterium animalis for childhood constipation

Condition

- Gastrointestinal conditions NEC

Synonym
constipation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bifidobacterium animalis, children, constipation, probiotics

Outcome measures

Primary outcome

Primary outcome measure:

Effect on stool frequency at 3 weeks.

Secondary outcome

Secondary outcomes:

- Effect on stool frequency over 3 weeks.

- Effect on stool consistency over 3 weeks.

- Effect on frequency of episodes of faecal incontinence over 3 weeks.

- Effect on pain during defecation over 3 weeks.

- Effect on digestive symptoms (abdominal pain and flatulence) over 3 weeks.

- Effect on adverse effects (nausea, diarrhea and bad taste) over 3 weeks.

- Effect on rate of success defined as three or more bowel movements per week and less than 1 faecal incontinence episode over the last 2 weeks of product consumption.

- Effect on rate of responders according to stool frequency at 3 weeks (a

responder will be defined as a subject who has a stool frequency of 3 or more

on the last week of product consumption).

- Effect on intake of Bisacodyl over 3 weeks.

Study description

Background summary

Chronic constipation is a common problem in childhood with an estimated prevalence of 3% in the western world.(1,2) Approximately 100.000 children in The Netherlands suffer from constipation. Constipation is a debilitating condition characterized by infrequent painful defecation, fecal incontinence and abdominal pain. It causes distress to child and family and results in severe emotional disturbance and family discord. Presently, there is no proper therapy available, mainly due to lack of pathophysiological insight. Approximately 50% of the constipated children have a low compliance taking oral laxatives for prolonged periods, mainly caused by side effects such as abdominal pain, nausea, diarrhea, flatulence, and bad taste of the different compounds. Low compliance is probably of major importance with respect to the low percentage of children cured after 6 months of laxative treatment. We hypothesize that the compliance increases by taking yoghurt containing Bifidobacterium animalis DN-173010. If this study indeed shows a significant better effect of BA compared to placebo, this will change the treatment of newly diagnosed children with constipation.

Recently, studies have shown that the bifidobacterium animalis strain DN-173010 (BA) significantly decreased colonic transit time in young and elderly healthy adults.(5-8) A recent randomized double-blind controlled trial in IBS patients with constipation (<3 bowel movements/week), showed a significant increase, as compared to control, in stool frequency over the 6-weeks BA consumption.(9) In a small pilot study in our centre 8 consecutive children with untreated constipation with a defecation frequency < 3 per week and hard stools were treated with BA 2 times/day for one month. A normalization of the defecation frequency and improvement from hard to soft stools were seen in five of them. In the three other children no improvement was found. None of the children reported side effects. A multi-centre RCT is now required to assess whether BA is effective in the treatment of childhood constipation.

Study objective

To determine the clinical effect and tolerance of BA in children with functional constipation aged 3-16 years.

Study design

Two nation (The Netherlands, Poland) multi-centre double-blind randomized controlled trial.

Intervention

The BA group will receive 2 times daily a fermented milk containing 125 g BA in combination with a bowel diary and toilet training. The placebo group will receive 2 times daily a bottle with a fermented milk in combination with a bowel diary and toilet training. In case defecation frequency is less than 3 times per week, bisacodyl 5mg two times per week will be given to the patient. Compliance of treatment will be evaluated by our standardized bowel diary. The study treatment will last 3 weeks.

Study burden and risks

There is no risk.

Burden could be considered as minimal (and not different from "conventional method"):
Clinical evaluation (and assessment of diaries) will be carried out at enrolment and at 3 weeks (each evaluation will last 20 minutes). This schedule of outpatient clinical visits is standard practice in order to enhance motivation and compliance of children and their parents with therapy.

Nowadays, these evaluations are also performed in standard therapy of constipated children.

This trial is important to perform in children because it is such an important pediatric health problem which can lead, if treated not sufficiently, to severe morbidity. Presently, there is no proper therapy available, mainly due to lack of pathophysiological insight. Furthermore, approximately 50% of the constipated children have a low compliance taking oral laxatives for prolonged periods, mainly caused by side effects such as abdominal pain, nausea, diarrhea, flatulence, and bad taste of the different compounds. Low compliance is probably of major importance with respect to the low percentage of children cured after 6 months of laxative treatment. We hypothesize that the compliance increases by taking yoghurt containing Bifidobacterium animalis DN-173010. If this study indeed shows a significant better effect of BA compared to placebo, this will change the treatment of newly diagnosed children with constipation.

Because of all prior mentioned reasons, we think it is of great importance that this trial will be performed in children and not in adults.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children (3 - 16 years of age) with untreated constipation fulfilling the Rome III-criteria: ;1) Defecation frequency < 3/week ;And at least 1 or more of the following criteria:
2) Fecal incontinence > 1 /week
3) Large amount of stools which clog the toilet
4) Painful defecation
5) Withholding behavior
6) Abdominal or rectal fecal impaction upon physical examination

Exclusion criteria

1) Children treated for constipation
2) Mental retardation / metabolic disease (hypothyroidism)
3) Hirschsprung*s disease / spinal anomalies / anorectal pathology
4) Children who underwent gastro-intestinal surgery
5) Children with functional non-retentive fecal incontinence
6) Children with cow's milk allergy

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL14086.018.07