Is Bifidobacterium breve effective in the treatment of childhood constipation?

Published: 20-11-2009
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Aim: Is the Bifidobacterium breve effective in the treatment of childhood constipation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON33537

Source
ToetsingOnline

Brief title
The Yic (Yoghurt in constipation) study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, stool problem

Research involving
Human

Sponsors and support

Primary sponsor: Yakult Nederland B.V.
Source(s) of monetary or material Support: Yakult Nederland BV

Intervention

Keyword: Bifidobacterium, Children, Constipation, Probiotics

Outcome measures

Primary outcome

Defecation frequency

Secondary outcome

- Stool consistency

- Pain during defecation

- The frequency of faecal incontinence episodes

- Adverse effects

- Use of Bisacodyl

Study description

Background summary

Approximately 100.000 children in The Netherlands suffer from constipation. Constipation is a debilitating condition characterized by infrequent painful defecation, involuntary loss of faeces in the underwear and abdominal pain. It causes distress to child and family and results in severe emotional disturbance and family discord. However, the compliance of taking medication is approximately 50%. Therefore there is a need for alternative laxative to succesfully treat children with constipation. Recently, a mixture of probiotics was effective in the treatment of childhood constipation. The hypothesis is that probiotics stimulate colonic motility and thus enhances defecation.
To date no studies are available evaluating the effect of the probiotic strain Bifidobacterium breve on childhood constipation.

Hypothesis: The probiotic strain Bifidobacterium breve results in a significant increase in defecation frequency in children with constipation.

Study objective

Aim: Is the Bifidobacterium breve effective in the treatment of childhood constipation.

Study design

This is a cohort pilot study.

Prior to the study enrolment, children and their parents record defecation frequency, consistency of stools, pain during defecation and frequency of episodes of faecal incontinence in a validated bowel diary for one week. At intake a general medical history and physical examination will be performed. Children fulfilling the Rome III criteria for childhood constipation will be offered to participate in the study.

The study protocol will last 6 weeks. All children receive one sachet of powder per day for 4 weeks. The patients are allowed to mix the powder with all liquids on condition that the liquid isn*t hot. The probiotics will be given in combination with toilet training. If a child does not defecate for three days during these 4 weeks, a stimulant laxative (bisacodyl 5-10 mg) will be prescribed on the fourth day. During the treatment phase defecation frequency, consistency of stools, pain during defecation and the frequency of episodes of faecal incontinence and possible adverse effects such as abdominal pain, bloating, flatulence, nausea, diarrhoea and bad taste will be recorded in a validated defecation diary.

After 4 weeks the study medication is stopped and a follow-up visit is scheduled at 6 weeks. Also during these 2 weeks defecation frequency, consistency of stools, pain during defecation and the frequency of episodes of faecal incontinence and possible adverse effects such as abdominal pain, bloating, flatulence, nausea, diarrhoea and bad taste will be recorded in a validated defecation diary.

Clinical evaluation and assessment of diaries will be carried out at enrolment and at 2, 4 and 6 weeks.

Intervention

intervention 1 sachet per day of powder with Bifidobacterium breve during 4 weeks

Study burden and risks

The scarce literature suggests that risk of infection with Lactobacilli or Bifidobacteria is similar to risks with commensal strains. There have been no serious adverse events reported in the treatment of children with Bifidobacteria.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

At least 2 or more of the following criteria for at least 8 weeks:
1. Defecation frequency <3/week
2. Faecal incontinence >1/week
3. Large amount of stools which clog the toilet
4. Painful defecation
5. Withholding behaviour
6. Abdominal or rectal faecal impaction upon physical examination

Exclusion criteria

1. Mental retardation/metabolic disease (hypothyroidism)
2. Hirschsprung's disease/ spinal abnomalies/ anorectal pathology
3. Children who underwent gastro-intestinal surgery
4. Children with functional non-retentive faecal incontinence
5. Use of laxatives two weeks prior to the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	20
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	NL25934.018.08