The effect of a mixture of probiotics on constipation symptoms in pregnant women

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Hypotheses1) The use of a combination of probiotic strains results in a significant increase in defecation frequency in pregnant women with constipation.2) The use of a combination of probiotic strains results in less episodes of difficult...

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

Summary

ID

NL-OMON33971

Source
ToetsingOnline

Brief title
Probiotics and constipation in pregnancy

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Constipation, Pregnancy, Probiotics

Outcome measures

Primary outcome

Primary study outcome measurement:

- Defecation frequency

- Episodes of difficult defecation as mentioned in the Rome III criteria

Secondary outcome

Secondary study outcome measurements:

- Stool consistency

- Sensation of incomplete evacuation

- Sensation of anorectal obstruction/ blockage

- Manual manoeuvres to facilitate defecation

- Abdominal pain

- Adverse effects: bloating, flatulence, nausea, diarrhoea and bad taste

- The presence of reflux episodes

- The presence of uterovaginal prolapse

- Use of Bisacodyl

Study description

Background summary

Constipation is a common symptom during pregnancy. Up to 40% of women will suffer from constipation symptoms at some stage during their pregnancy. Already in early pregnancy defecation symptoms are reported, most of them already present at 12 weeks gestation. Constipation is one of the most common

gastrointestinal conditions affecting 12-27% of the general population. Pregnant women may experience constipation for the first time during pregnancy or find their constipation symptoms worsening, if constipated prior to pregnancy, during pregnancy. Apart from the discomfort of constipation symptoms, it has also the potential to cause permanent damage. There is evidence that straining to defecate can damage the pudendal nerve and impair the supportive function of the pelvic floor musculature. Constipation is also an important factor in developing uterovaginal prolapse.

To date, no trials have been performed to show the effect of a mixture of probiotics on constipation symptoms in pregnant women. One adult study showed an increase in defecation frequency in those receiving two strains of probiotics. One paediatric pilot study showed that a mixture of probiotics containing lactobacilli and bifidobacteria augments the defecation frequency in those presenting with less than 3 bowel movements per week.

In collaboration with Winclove Bio Industries a new combination of probiotics is developed for treatment of constipation. In a pilot study performed in constipated children using the same combination of probiotics has shown positive effects on gastro-intestinal symptoms such as abdominal pain without side effects. Further studies need to be done to elucidate the role of a mixture of probiotics in treating constipated pregnant women. This is of importance as patients on general in daily practice seem to prefer probiotics over medication, certainly during pregnancy. In concordance with the guidelines for treatment of constipation during pregnancy, set up by a group of experts in 2003, non-pharmalogical measures are the first step in treatment. Probiotics are candidates as a non-pharmalogical modification in treating constipation during pregnancy.

Study objective

Hypotheses
1) The use of a combination of probiotic strains results in a significant increase in defecation frequency in pregnant women with constipation.

2) The use of a combination of probiotic strains results in less episodes of difficult defecation, as described in the Rome III criteria in pregnant women with constipation.

Study design

Prior to the study enrolment, pregnant women record defecation frequency, consistency of stools, pain during defecation and the 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. Subjects fulfilling the Rome III criteria for constipation will be offered to

participate in the study.

Before study medication is given, all subjects will receive one enema (Klyx 120 ml (Sodium dioctylsulfosuccinate) once daily for three days to clear any faecal remains. Study probiotics contain the following 6 probiotic strains:
- Bifidobacterium bifidum
- Bifidobacterium infantis
- Bifidobacterium longum
- Lactobacillus casei
- Lactobacillus plantarum
- Lactobacillus rhamnosus

The study protocol will last 6 weeks. All subjects receive 1dd 4 gram (4x109 CFU) of the probiotic strains for 4 weeks. The probiotics will be given with a glass of water. If a subject 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

Study probiotics contain the following 6 probiotic strains:
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Study burden and risks

None

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Pregnant women
- Constipation as defined by the Rome III criteria
- Third trimester

Exclusion criteria

- Use of any laxatives 4 weeks before intake
- Gastro-intestinal surgery in the medical history
- Metabolic disease explaining constipation symptoms

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
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	NL20224.018.07