Effectiveness of probiotics of children with chronic abdominal pain en bacterial overgrowth.

No registrations found.

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

Summary

ID

NL-OMON20319

Source
Nationaal Trial Register

Brief title
SIBO study

Health condition

chronic abdominal pain, small intestinal bacterial overgrowth

Sponsors and support

Primary sponsor: Jeroen Bosch hospital, Den Bosch
Source(s) of monetary or material Support: Winclove Bio Industries, Amsterdam
Orthica, Almere

Intervention

Outcome measures

Primary outcome

The reduction of abdominale pain is our primairy outcome. Abdominale pain is measured by an abdominal pain diary. Patients will be instructed to score pain intensity and pain

frequency during 1 month at baseline period, after finishing the treatment and at 6 and 12 months follow up. Clinical remission is defined as a decrease of the pain intensity score and pain frequency score of > 80%; significant improvement is defined as a decrease of pain intensity score and pain frequency score between 30% and 80% and treatment is considered unsuccessful if the scores improved < 30% or got worse.

Secondary outcome

Secondary outcome measures is the presence of small intestinal bacterial overgrowth.

Study description

Background summary

Background: Chronic abdominal pain is a common problem of school-going children and is one of the most frequent reasons to visit a pediatrician. Pathogenesis remains unclear. Recent studies have pointed to an underlying gut microbial mechanism for chronic abdominal pain. When the microbial population native to the large intestine migrates proximally into the small intestine, a shift in the host-gut microbial relationship occurs, known as small intestinal bacterial overgrowth (SIBO). Similar to children with chronic abdominal pain, children with SIBO complain of nausea, abdominal pain, flatulence, diarrhoea and constipation. Scarpellini et al. showed an association between small intestine bacterial overgrowth and irritable bowel syndrome in children. Therapeutic options are limited. Recent study results showed that 70% of children with chronic abdominal pain and small intestinal bacterial overgrowth have an improvement of symptoms after treatment with probiotics. Although these data are promising, the study group was small and it missed a control group.

Aim: The aim of this study is to compare the effect of probiotics on chronic abdominal pain and small intestinal bacterial overgrowth compared to placebo.

Methods: 70 children, aged between 8-18yrs, with chronic abdominal pain and bacterial overgrowth will be randomized to one of these treatments: probiotics or placebo. Primary outcome measures are the percentages of patients with complete remission of chronic abdominal pain after the treatment phase and at six and twelve months follow up. Secondary outcome measures is the presence of small intestinal bacterial overgrowth.

Study objective

Children with chronical abdominal pain and small intestinal bacterial overgrowth supplemented with probiotics will show less abdominal pain compared to placebo.

Study design

Outcomes are assessed at:

t=0: baseline; before randomisation;

t=1: directly after finishing the treatment period;

t=2: six months follow up;

t=3: twelve months follow up.

Intervention

The probiotics consist of a mixture of Bifidobacterium and Lactobacillus (8 grams of powder 4 x 10E9 cfu Bifidobacterium and Lactobacillus (Ecologic junior)). This has te be used once a day for 8 weeks.

The control group will receive a placebo (Placebo is a composition of rice starch, maltodextrins and vegetable protein, and contains no bacterial strains).

Contacts

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Eligibility criteria

Inclusion criteria

Children aged 8-18 years are included if they meet the criteria for functional dyspepsia, IBS, functional abdominal pain (FAP) or abdominal migraine, based on the Rome III Criteria for Functional Bowel Disorders Associated with Abdominal Pain or Discomfort in Children and have small intestinal bacterial overgrowth, diagnosed on hydrogen breath test as a fasting breath hydrogen concentration > 20 ppm or an increase of H2 levels of > 12 p.p.m. over the baseline value after ingestion of glucose.

Exclusion criteria

1. Children with abdominal pain as result of inflammatory, anatomic, metabolic or neoplastic disease;

2. Children who were prescribed antibiotics or probiotics in the last month;

3. Children who are critically ill or admitted at the ICU. Children who receive feeding via a tube.

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):	01-03-2012
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39168
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3141
NTR-old	NTR3285
CCMO	NL39061.028.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39168

Study results

Summary results
N/A