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

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

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

Samenvatting

ID

NL-OMON20319

Bron
Nationaal Trial Register

Verkorte titel
SIBO study

Aandoening

chronic abdominal pain, small intestinal bacterial overgrowth

Ondersteuning

Primaire sponsor: Jeroen Bosch hospital, Den Bosch
Overige ondersteuning: Winclove Bio Industries, Amsterdam
Orthica, Almere

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-03-2012
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-02-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39168
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A