Enema versus high doses of PEG 3350 in the treatment of rectal fecal impaction.

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1. High dose of PEG is more effective and more tolerable in the treatment of fecal impaction compared to rectal enemas; 2. Fecal impaction results in a delayed colonic transit time, which will improve during successful disimpaction.

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

Samenvatting

ID

NL-OMON23431

Bron
NTR

Verkorte titel
the Leopard study

Aandoening

Childhood constipion

Ondersteuning

Primaire sponsor: geen
Overige ondersteuning: geen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Rectal fecal impaction evaluated by rectal examination/abdominal x-ray.

Toelichting onderzoek

Achtergrond van het onderzoek

Enema versus high doses of PEG 3350 in the treatment of fecal impaction
“the Leopard Study”.

Background:

Fecal retention with stasis (impaction) of stools in the rectum is a common symptom of childhood constipation. Fecal impaction is defined as severe constipation with a large fecal mass which is unlikely to be passed on demand. It includes a dilated rectum filled with a large amount of (usually) hard stool, noted either by abdominal palpation or rectal examination. The conventional therapy in these children is rectal enemas followed by a maintenance dose of PEG. The purpose of this study is to investigate whether high dose of PEG solution is more efficient in the treatment of rectal fecal impaction. If so the need for rectal enemas will diminish significantly and will lead to another guideline for the first line treatment of these children.

It is suggested that a distended rectum slows down the motor activity of the colon and that an inhibitory recto-colonic feedback mechanism exists. The effect of the rectal distension due to fecal impaction on the colonic motility is not understood. To evaluate the latter mechanism in children with rectal fecal stasis the effect of fecal impaction on the CTT in these children will be investigated, by assessing the difference between the CTT in a non-prepared impacted rectum and the CTT during clearance of fecal impaction with intensive laxative therapy.

Aim:

1. To investigate the efficacy of high doses of PEG 3350 versus rectal enemas in the treatment of fecal impaction in children with chronic constipation.

2. To assess whether the colonic transit time is longer during fecal impaction than when the impaction is resolved.

Study population:

Ninety children (4-18 years) with constipation referred to the outpatient clinic at Emma Children’s Hospital/AMC with evidence of rectal fecal impaction will be offered to enroll in the study.

Methods:

This is a prospective randomized controlled study, with a non-inferiority design.
Abdominal and rectal examination is acquired by the physician to define the presence of fecal impaction, which is defined as a large fecal mass of hard stools in the rectum. After intake, on 6 consecutive days, all patients will ingest 1 capsule with 10 radio-opaque markers to assess the colonic transit time. During these days, no laxative medication will be given and a diary is filled out by child and parents. On day 7 an abdominal radiograph is obtained.

Subsequently on day 8 the disimpaction therapy will be started with either 6 days of enemas or 6 days of PEG, according to randomization. A diary is filled out by child and parents. During this study period the colonic transit time will be measured again, according to the above described method. On day 14, a second abdominal radiograph is obtained. The presence or absence of fecal impaction is assessed by abdominal and rectal examination. Thereafter, all patients receive laxative medication (enemas or PEG 3350) according to their defecation pattern and symptoms. A second follow-up visit will be scheduled on day 28 and diaries will be reviewed regarding symptoms and possible adverse effects.

Doel van het onderzoek

1. High dose of PEG is more effective and more tolerable in the treatment of fecal impaction compared to rectal enemas;

2. Fecal impaction results in a delayed colonic transit time, which will improve during successful disimpaction.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

At intake a standardized questionnaire is obtained by a physician to the parents and patient. Physical examination, including abdominal and rectal examination is acquired by the physician to define the presence of fecal impaction. Fecal impaction is defined as a large fecal mass of hard stools in the rectum.
After intake, on 6 consecutive days, all patients will ingest 1 capsule with 10 radio-opaque markers to assess the colonic transit time. During these days, no laxative medication will be given and a diary is filled out by child and parents. On day 7 an abdominal radiograph is obtained.
Subsequently on day 8 the disimpaction therapy will be started with either 6 days of enemas or 6 days of PEG, according to randomization. A diary is filled out by child and parents. This diary concerns topics on defecation pattern, fecal incontinence, abdominal pain and possible side effects of administered medications. During this study period the colonic transit time will be measured again, according to the above described method.

On day 14, a second abdominal radiograph is obtained to measure colonic transit time. The presence or absence of fecal impaction is assessed by abdominal and rectal examination as well as by the second abdominal X-ray.

Thereafter, all patients receive laxative medication (enemas or PEG 3350) according to their defecation pattern and symptoms. A second follow-up visit will be scheduled on day 28 and diaries will be reviewed regarding symptoms and possible adverse effects.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 4-18 years;

2. Fecal impaction upon rectal exam.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous colonic surgery;

2. Organic cause of constipation;

3. Allergy/sensitivity to PEG solutions or phosphates;

4. Allergy/sensitivity to sodium ducosate or sorbitol (“Klyx” enema).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-02-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL546
NTR-old	NTR602
Ander register	: N/A
ISRCTN	ISRCTN71579145

Resultaten

Samenvatting resultaten
N/A