

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

Submission date 08/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/03/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/04/2009	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M A Benninga

Contact details
Academic Medical Centre (AMC)
Department of Pediatrics
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 3053
m.a.benninga@amc.nl

Additional identifiers

Protocol serial number
NTR602

Study information

Scientific Title

Acronym

The Leopard study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee

Primary study design

Interventional

Study design

Prospective randomised controlled study with a non-inferiority design

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Constipation

Interventions

At intake a standardised questionnaire is obtained by a physician from the parents and patient. Physical examination, including abdominal and rectal examination is acquired by the physician to define the presence of faecal impaction. Faecal impaction is defined as a large faecal mass of hard stools in the rectum.

After intake, on 6 consecutive days, all patients will ingest one 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 randomisation. A diary is filled out by the child and the parents. This diary concerns topics on defecation pattern, faecal 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 faecal 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 defaecation 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.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

PEG 3350

Primary outcome(s)

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

Key secondary outcome(s)

1. Defaecation frequency/week
2. Faecal incontinence frequency/week
3. The number of side effects, such as abdominal pain, bloating, flatulence, nausea, bad taste
4. Total and segmental colonic transit time

Completion date

01/08/2007

Eligibility**Key inclusion criteria**

1. Aged 4 - 18 years
2. Faecal impaction upon rectal exam

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 Years

Upper age limit

18 Years

Sex

All

Key exclusion criteria

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)

Date of first enrolment

01/01/2006

Date of final enrolment

01/08/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands) - Department of Pediatrics

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration