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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 16/04/2009	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective randomised controlled study with a non-inferiority design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2006

Completion date
01/08/2007

Eligibility

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

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
90

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)

Sponsor details
Department of Pediatrics
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration