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The effect of loperamide in childhood idiopathic faecal incontinence: the compensation reflex of the anorectal complex and clinical outcome

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/09/2009	**Condition category** Signs and Symptoms	[_] 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 Center
Pediatric Department
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5663053
m.a.benninga@amc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR399

Study information

Scientific Title

Study objectives
1. We hypothesise that children with solitary encopresis have a disturbed compensation reflex, eventually combined with aberrant huge rectal contractions
2. We hypothesise that in children with solitary encopresis loperamide rectally given, will reduce rectal activity and consequently exert its clinical effect

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised double blind placebo controlled crossover group trial

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
Encopresis, solitary

Interventions
Period 1: 1 month suppositories either placebo or loperamide twice daily 5 mg + diary chart. Combine rectal manometry and barostat at end of period.
Period 2: 1 month wash-out + diary chart.
Period 3: 1 month suppositories either placebo or loperamide twice daily 5 mg + diary chart. Combine rectal manometry and barostat at end of period.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Encopresis frequency
2. Rectal function: comparison between loperamide and placebo period

Secondary outcome measures
3. Side effects of loperamide suppositories

Overall study start date
01/01/2003

Completion date
01/08/2005

Eligibility

Key inclusion criteria
To enter the study the patients have to fulfil the following criteria:
1. Encopresis frequency of ≥ 2 times/week
2. Colonic transit time ≥ 62 hours
3. At least 3 years treatment without success (biofeedback training, laxatives, toilet training)
4. Age of the child ≥ 8 years

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Colonic transit time >62 hours
2. Other signs of constipation:
2.1. Defecation frequency <2 times per week
2.2. Periodic passage of very large amounts of stool
2.3. A palpable abdominal or rectal mass
3. Anorectal malformations
4. Impaired neurological functioning such as spina bifida
5. Evident psychiatric diagnosis such as depressive disorder
6. Metabolic diseases
7. Using drugs influencing gastrointestinal motility
8. Mental retardation
9. Any abdominal or anorectal surgical intervention

10. Hirschsprungs disease
11. Any other (gastrointestinal) disease with a possible influence on gastrointestinal motility

Date of first enrolment
01/01/2003

Date of final enrolment
01/08/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (Netherlands)

Sponsor details
Pediatric Department
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

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