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

Submission date	Recruitment status	Prospectively registered
27/01/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
27/01/2006	Completed	Results
Last Edited	Condition category	Individual participant data
01/09/2009	Signs and Symptoms	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 1. Encopresis frequency
- 2. Rectal function: comparison between loperamide and placebo period

Key secondary outcome(s))

3. Side effects of loperamide suppositories

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 \geq 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 \geq 8 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

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)

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