

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	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/09/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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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

Primary study design

Interventional

Study design

Randomised double blind placebo controlled crossover group trial

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 ≥ 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

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