

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

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/09/2009	<b>Condition category</b> Signs and Symptoms	<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

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](mailto: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  $\geq 2$  times/week
2. Colonic transit time  $\geq 62$  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

**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