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# Are enemas indicated for treatment of children with solitair encopresis?

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|---|---|---|
| **Submission date**<br>12/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>12/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/01/2021 | **Condition category**<br>Signs and Symptoms | |

**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**
NTR65

# Study information

### Scientific Title
Are enemas indicated for treatment of children with solitair encopresis?

### Study objectives
The use of enemas will result in a empty rectum and no more soiling or encopresis. In this period these children will experience and get used to a clean feeling and the advantages. This might lead to a better motivation for treatment of solitair encopresis.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the local medical ethics committee

### Study design
Randomised open label active controlled parallel group trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Functional non-retentive faecal soiling

### Interventions
Group one: enemas following a schedule during three months
Group two: no laxantia, but education and toilet training

The anticipated end date of this trial was increased to the 31st December 2006.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure

1. Defecation frequency
2. Soiling/encopresis frequency
3. Stool consistency

Patients will visit our out-patient visits for follow-up at several fixed moments: intake and t = one week, two weeks, four weeks, six weeks, 12 weeks, 6 months, 12 months. During this study, all patients will record in a specific diary on primary and secondary outcome measurements.

### Secondary outcome measures
Tolerance of enemas: abdominal pain, painful defecation, nausea, vomiting, flatulency.

### Overall study start date
01/03/2002

### Completion date
01/03/2005

## Eligibility

### Key inclusion criteria
1. Aged 8 to 17 years
2. Functional Non-Retentive Faecal Soiling (FNRFS) criteria:
2.1. defaecation frequency three times a week
2.2. encopresis frequency more than once a week
2.3. no faecal impaction with physical examination

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
17 Years

### Sex
Both

### Target number of participants
78

### Total final enrolment
71

### Key exclusion criteria
1. Gastro-intestinal surgery
2. Anorectal anomaly

3. Mental retardation
4. Constipation

**Date of first enrolment**
01/03/2002

**Date of final enrolment**
01/03/2005

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Academic Medical Centre**
Amsterdam
Netherlands
1105 AZ

# Sponsor information

**Organisation**
Academic Medical Centre (AMC) (Netherlands)

**Sponsor details**
Pediatric Department
Meibergdreef 9
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1105 AZ

**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)

# 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2013 | 07/01/2021 | Yes | No |