

Are enemas indicated for treatment of children with solitair encopresis?

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/01/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Tolerance of enemas: abdominal pain, painful defecation, nausea, vomiting, flatulency.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

17 years

Sex

All

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)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands)

Results and Publications

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