

The effect of additional use of enemas versus the standard treatment of chronic constipation in children

Submission date 04/08/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 04/08/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 11/06/2008	Condition category Digestive System	☐ Individual participant data
		☐ 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

NTR36

Study information

Scientific Title

Study objectives

1. Early intervention with oral and rectal laxatives will lead to a higher success percentage compared to standard treatment in constipated children
2. Long lasting fecal stasis leads to abnormal rectal functions (compliance and sensation)
3. Early frequent rectal laxatives prevent irreversible damage to rectal function

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee

Study design

Randomised, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Constipation

Interventions

Group 1: weekly enemas and standard treatment

Group 2: standard treatment with oral laxative (movicolon)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Movicolon

Primary outcome(s)

1. Defecation frequency
2. Soiling/encopresis frequency
3. Stool consistency
4. Use of laxatives

Patients will visit our out-patient visits for follow-up at several fixed moments: intake and t = 2 weeks, 4 weeks, 6 weeks, 12 weeks, 26 weeks, 39 weeks and 52 weeks. During this study, all patients will record in a specific diary on primary outcome measurements.

Key secondary outcome(s))

Rectal compliance and sensation at $t = 0$ and $t = 52$ weeks. A barostat is performed in all children pre-treatment and after one year of treatment and rectal functions are determined (rectal compliance and sensation). The results of $t = 0$ and $t = 52$ weeks are compared to assess possible differences in rectal function.

Completion date

01/12/2005

Eligibility

Key inclusion criteria

1. Rome II criteria for constipation
2. Aged 8 - 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. Hirschsprung's disease
2. Gastrointestinal surgery
3. Anorectal anomaly
4. Metabolism disorders
5. Mental retardation

Date of first enrolment

01/01/2003

Date of final enrolment

01/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration