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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2005	**Overall study status** Completed	
Last Edited 11/06/2008	**Condition category** Digestive System	

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
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