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

Submission date	Recruitment status	[ ] Prospectively registered
04/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/08/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/06/2008	Digestive System	[ ] Record updated in last year

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
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

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2003

Completion date
01/12/2005

Eligibility

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

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
100

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)

Sponsor details
Emma Kinderziekenhuis
Postbus 22660
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The 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