

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/06/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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