

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22780

Source

NTR

Brief title

N/A

Intervention

Outcome measures

Primary outcome

Defecation frequency, soiling/encopresis frequency, stool consistency; 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

Rectal compliance and sensation at t=0 en t=52 weeks; A barostat is performed in all children pre-treatment and after 1 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.

Study description

Background summary

N/A

Study objective

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.

Study design

N/A

Intervention

Group 1: weekly enemas + standard treatment;

Groep 2: standard treatment with oral laxantia (movicolon).

Contacts

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Eligibility criteria

Inclusion criteria

Rome II-criteria for constipation, age 8-18 year.

Exclusion criteria

1. Hirschsprung's disease;
2. gastro-intestinal surgery;
3. anorectal anomaly;
4. metabolism disorders;
5. mental retardation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2003
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion	
Date:	21-06-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL18
NTR-old	NTR36
Other	: N/A
ISRCTN	ISRCTN99089299

Study results

Summary results

N/A