

Forlax versus Transipeg in constipated children.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20023

Source

Nationaal Trial Register

Brief title

N/A

Health condition

1. Constipation;
2. fecal incontinence;
3. abdominal pain.

Sponsors and support

Primary sponsor: Emma Children's Hospital

Source(s) of monetary or material Support: Emma Children's Hospital

Intervention

Outcome measures

Primary outcome

1. Defecation frequency;

2. Frequency of faecal incontinence episodes.

Secondary outcome

Abdominal pain.

Study description

Background summary

Children presenting at the outpatient clinics of the gastroenterology of the Emma Children's hospital will be randomised to either Forlax or Transipeg as a laxans therapy. The difference between the two agents in success will be evaluated at the end of the study.

Study objective

Forlax and transipeg are equally effective in treating childhood constipation.

Study design

N/A

Intervention

None, because the children would be treated by laxants anyway. For this reason we don't assume treatment as an intervention.

Contacts

Public

Emma Children's hospital
Department of paediatric gastroenterology
Postbus 22660
N. Bekkali
Amsterdam 1100 DD
The Netherlands
+31-205662906

Scientific

Emma Children's hospital
Department of paediatric gastroenterology
Postbus 22660

N. Bekkali
Amsterdam 1100 DD
The Netherlands
+31-205662906

Eligibility criteria

Inclusion criteria

1. Infants between 6 months and 15 years;
2. Defecation frequency < 3/week;
3. No oral laxatives for 2 weeks;
4. No PEG-laxatives for 2 months.

Exclusion criteria

1. Metabolic disease;
2. functional non-retentive faecal incontinence;
3. mental retardation;
4. cerebral palsy;
5. anal anomalies;
6. Hirschsprung's disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	04-03-2006
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion	
Date:	11-09-2007
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	NL1065
NTR-old	NTR1098
Other	: Transipeg-Forlax studie
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A