The effect of loperamide in childhood idiopathic faecal incontinence: the compensation reflex of the anorectal complex and clinical outcome.

No registrations found.

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

Summary

ID

NL-OMON25869

Source
Nationaal Trial Register

Brief title
N/A

Health condition

solitary encopresis in children

Sponsors and support

Source(s) of monetary or material Support: AMC, pediatric department

Intervention

Outcome measures

Primary outcome

1. Encopresis frequency;

2. Rectal function: comparison between loperamide and placebo period.

Secondary outcome

Side effects loperamide supps.

Study description

Background summary

Trail in order to reveal the effect of loperamide on solitairy encopresis in children.
The effect is clinically assessed through diary charts during three periods, 1 with loperamide, 1 wash-out, and 1 placebo period.
Furthermore, the effect of loperamide on the anorectal function is assessed through a combined anorectal manomatry and barostat measurement.

Study objective

1. We hypothesize that children with solitary encopresis have a disturbed compensation reflex, eventually combined with aberrant huge rectal contractions;

2. We hypothesize that in children with solitary encopresis loperamide rectally given, will reduce rectal activity and consequently exert its clinical effect.

Intervention

period 1: 1 month suppositories either placebo or loperamide twice daily 5 mg + diary chart

- combine rectal manometry and barostat at end of period

periode 2: 1 month wash-out + diary chart

period 3: 1 month suppositories either placebo or loperamide twice daily 5 mg + diary chart

- combine rectal manometry and barostat at end of period.

Contacts

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Eligibility criteria

Inclusion criteria

To enter the study the patients have to fulfil the following criteria:

1. Encopresis frequency of = of > 2 times / week;

2. Colonic transit time < or = 62 hours;

3. At least 3 years treatment without success (biofeedback training, laxatives, toilet training);

4. Age of the child = or > 8 yrs.

Exclusion criteria

1. Colonic transit time > 62 uur;

2. Other signs of constipation:

a. Defecation frequency < 2 times per week; or

b. Periodic passage of very large amounts of stool; or

c. Palpable abdominal or rectal mass;

3. Anorectal malformations;

4. Impaired neurological functioning such as spina bifida;

5. Evident psychiatric diagnosis such as depressive disorder;

6. Metabolic diseases;

7. Using drugs influencing gastrointestinal motility;

8. Mental retardation;

9. Any abdominal or anorectal surgical intervention;

10. Hirschsprung’s disease;

11. Any other (gastrointestinal) disease with a possible influence on gastrointestinal motility.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2003
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	13-09-2005
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	NL360
NTR-old	NTR399
Other	: N/A
ISRCTN	ISRCTN43733247

Study results

Summary results
N/A