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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25869

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

solitary encopresis in children

Ondersteuning

Overige ondersteuning: AMC, pediatric department

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Encopresis frequency;
2. Rectal function: comparison between loperamide and placebo period.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2003
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2005

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL360
NTR-old	NTR399
Ander register	: N/A
ISRCTN	ISRCTN43733247

Resultaten

Samenvatting resultaten
N/A