Treatment of childhood constipation in general practice.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27168

Source
Nationaal Trial Register

Health condition

childhood constipation, paediatric physiotherapy, primary care

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

To asses the feasibility of conducting a RCT comparing the effect of paediatric physiotherapy with the effect of laxative treatment on symptoms of functional constipation in children in primary care.

Secondary outcome

1. Treatment succes;

2. Quality of life;

3. Medication use;

4. Costs.

Study description

Background summary

Constipation is the most common gastro-intestinal disorder in childhood. Laxative treatment is currently recommended as the first choice therapy for children with functional constipation in primary care (usual care). However, while the effect of paediatric physiotherapy is not yet evidence-base, this therapy might also be helpful for children with functional constipation in primary care. Furthermore it is unknown if there is a difference in medication use, quality of life and costs when these two treatments are compared with each other.

Study objective

Pelvic physiotherapy is more effective than usual care (laxatives) for the treatment of functional constipation.

Study design

Follow-up at 12 and 24 weeks. Measurements will be taken through questionnaires and a stool diary.

Intervention

Comparison of a treatment with laxatives with a peadiatric treatment for functional childhood constipation in primary care. The peadiatric treatment focusses on toilet training; how they should relax and breath. Laxatives will be prescribed as usual. Both interventions have a maximum of 24 weeks. Treatment will be stopped if there are no more complaints or when the treating doctor thinks further treatment is without value.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 4-17 years;

2. Functional constipation defined by the NHG Standaard Obstipatie as having at least two of the following symptoms:

A. Defecation ≤ 2 per week;

B. Cessation of defecation;

C. Painful, lumpy or hard defecation;

D. Large diameter stools that may obstruct the toilet;

E. Presence of a large faecal mass in the rectum or abdomen;

F. ≥ 1 episode of faecal incontinence per week.

Exclusion criteria

1. Terminal illness;

2. Mental retardation;

3. Metabolic disease (e.g. hypothyreoidi);

4. Hirchsprung disease/ spine anomalies/ anorectal pathology (e.g. hemorrhoids, anal fissure, perirectal abscess, pruritis ani, fecal incontinence);

5. Gastrointestinal surgery in medical history;

6. Presence of an indication for referral to secondary care: suspicion for ileus, Hirchsprung disease, anatomic malformation or pelvic floor pathology, severe behavioural problems, developmental problems or a disturbed parent-child relationship concerning defecation;

7. Contraindication for PEG3350 electrolytes (e.g.Toxic megacolon, Inflammatory bowel disease, acute abdominal pain, allergies for one of the substances);

8. Children who already receive laxative treatment prescribed by the GP or children for who it's less than 3 months ago that they stopped taking laxatives.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3715
NTR-old	NTR3878
CCMO	NL43786.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A