Laxative therapy in children with functional abdominal pain

No registrations found.

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

Summary

ID

NL-OMON24535

Source
Nationaal Trial Register

Health condition

Functional abdominal pain. Chronic abdominal pain. Children. Laxatives. Rome criteria.

Sponsors and support

Primary sponsor: Haga Teaching Hospital, loc Juliana Children's Hospital
Els Borst-Eilersplein 275, 2545 AA The Hague
Source(s) of monetary or material Support: CZ-Fonds,
Tilburg

Intervention

Outcome measures

Primary outcome

Pain score (Wong-Baker Faces Pain Score): % with score 0 (pain free)

Secondary outcome

Pain score: % decrease of pain in last week of intervention phase versus last week of run-in phase.

Study description

Background summary

In a double blind randomised controlled study, children (age 4-16 years) have a 4 week course of the laxative macrogol 4000 versus placebo with the percentage of pain free patients as first outcome measure and the percentage decrease of pain score as second outcome measure.

Study objective

Because of the impact of chronic abdominal pain in children and the long term prognosis with impressive consequences for the life of the patients and for the society, it is important to aim at optimal therapy. Standard therapy is rather ineffective. In an earlier observational study, we had good result with laxative therapy. This needs to be confirmed in a randomised placebo-controlled trial.

Hypothesis 1. In children with functional abdominal pain, laxative therapy leads to a significant reduction of pain.

Hypothesis 2. This effect will be found independent of the presenting Rome IV functional abdominal pain disorder (functional dyspepsia, irritable bowel syndrome or functional abdominal pain-NOS)

Study design

4 weeks and 6 months (follow up)

Intervention

Macrogol 4000, starting dosage 20 g/day, to increase every 2 days with 10 g in case of insufficient result until a maximum dosage of 50 g/day. The dosage should be adjusted guided by the stool consistency with the help of the (adjusted) Bristol Stool Form Scale. The intervention has a total duration of 4 weeks.

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Eligibility criteria

Inclusion criteria

1. Age 4-16 years

2. Fulfilling the Rome IV criteria for functional abdominal pain disorders, with exception of the criterion for IBS-patients that the pain does not resolve with resolution of constipation

Exclusion criteria

1. Insufficient knowledge of the Dutch language

2. Earlier therapy with generic macrogol

3. Participation of a sibling in the study

4. Abdominal pain less than 2x per week in the diagnostic phase according to diary

5. Diagnosis 'functional constipation' according to the Rome IV criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-11-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-11-2016
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	NL5930
NTR-old	NTR6110
Other	EudraCT, ABR dossier : 2014-005467-32, NL57969.098.16

Study results