Laxative therapy in children with functional abdominal pain

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24535

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Haga Teaching Hospital, loc Juliana Children's Hospital
Els Borst-Eilersplein 275, 2545 AA The Hague
Overige ondersteuning: CZ-Fonds,
Tilburg

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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)

Onderzoeksopzet

4 weeks and 6 months (follow up)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	24-11-2016
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-11-2016
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	NL5930

Register	ID
NTR-old	NTR6110
Ander register	EudraCT, ABR dossier : 2014-005467-32, NL57969.098.16

Resultaten