

An Evaluation of Patient Experience, Quality of Life, and Independence in Pediatric Patients with Functional Constipation Using Transanal irrigation with Navina Systems

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With this study we expect to generate important knowledge about treatment experience, treatment adherence, and quality of life of children using TAI with a Navina system. If we can identify factors that affect either one of those, pediatric...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20284

Bron

Nationaal Trial Register

Verkorte titel

TAI in children with constipation

Aandoening

Constipation

Ondersteuning

Primaire sponsor: Wellspect

Overige ondersteuning: Non-restricted research grant from Wellspect

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Treatment success defined as at least 2 bowel movements per week and less than one episode of fecal incontinence per week at 1-month, 6-months, and latest follow-up

Toelichting onderzoek

Achtergrond van het onderzoek

The objective of our study is to retrospectively investigate the clinical effectiveness of children with constipation using a Navina transanal irrigation (TAI) system. Secondary objective is to cross-sectionally investigate patient empowerment and treatment independence and their relation with health-related quality of life and treatment adherence in pediatric patients with constipation treated with TAI. In addition, we will assess patient use, patient experience and the safety of the device.

Doel van het onderzoek

With this study we expect to generate important knowledge about treatment experience, treatment adherence, and quality of life of children using TAI with a Navina system. If we can identify factors that affect either one of those, pediatric healthcare professionals may be able to adjust their approach or therapy accordingly. We hypothesize that the health-related quality of life of children with constipation using TAI is lower compared to children with constipation in general and may be affected by the experienced patient empowerment and treatment independence. We hypothesize that treatment adherence of children treated with TAI is higher compared to children only treated with laxatives.

Onderzoeksopzet

Retrospective part: baseline, 1 month follow-up, 6 month follow-up, and latest follow-up.
Cross-sectional: single time point.

Onderzoeksproduct en/of interventie

Questionnaires

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children with constipation, both functional constipation based on Rome IV- criteria and constipation with an organic cause, who have been treated with transanal irrigation for at least one month.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For cross-sectional part: limited knowledge of Dutch language

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-07-2021
Aantal proefpersonen: 30
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 25-08-2021
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	NL9691
Ander register Medical Ethics Review Committee AMC : W21_240 # 21.267	

Resultaten