

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20284

### Source

NTR

### Brief title

TAI in children with constipation

### Health condition

Constipation

## Sponsors and support

**Primary sponsor:** Wellspect

**Source(s) of monetary or material Support:** Non-restricted research grant from Wellspect

## Intervention

## Outcome measures

### Primary outcome

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

## **Secondary outcome**

To cross-sectionally investigate patient empowerment, treatment adherence, and health-related quality of life of children with functional constipation using TAI with a Navina system. Last, a self-developed questionnaire will be used to evaluate patient experience with the transanal irrigation system, adverse effects, and treatment independence (including time spent on bowel management and patient satisfaction).

# **Study description**

## **Background summary**

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.

## **Study objective**

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.

## **Study design**

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

## **Intervention**

Questionnaires

## Contacts

### **Public**

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### **Scientific**

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## Eligibility criteria

### **Inclusion criteria**

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.

### **Exclusion criteria**

For cross-sectional part: limited knowledge of Dutch language

## Study design

### **Design**

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-07-2021  
Enrollment: 30  
Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 25-08-2021  
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	NL9691
Other	Medical Ethics Review Committee AMC : W21_240 # 21.267

## Study results