

# Prognostic Factors in treatment of Functional Childhood Constipation. A multicenter observational cohort study in the Netherlands. (The PROFUNCO Study)

Published: 27-08-2015

Last updated: 15-02-2025

This study had two objectives: 1. which factors determine outcome of treatment of children with functional childhood constipation referred to the outpatient clinic of multidisciplinary treatment clinics in the Netherlands; 2. which factors can be...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal motility and defaecation conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON41542

### Source

ToetsingOnline

### Brief title

The PROFUNCO Study

### Condition

- Gastrointestinal motility and defaecation conditions

### Synonym

functional constipation

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Maastricht University

**Source(s) of monetary or material Support:** subsidie aanvraag is in behandeling

## Intervention

**Keyword:** children, functional constipation, prognosis

## Outcome measures

### Primary outcome

A sustained response to treatment 6 months after start of treatment, defined as: the patient having a stool frequency of at least three times weekly, without fecal incontinence. Sustained response is defined as successfully treated as defined above in the absence of relapse of symptoms, and irrespective of laxative treatment. At 6 months patients are considered either responder or non-responder to therapy.

### Secondary outcome

not applicable

## Study description

### Background summary

Functional constipation in childhood is a chronic condition, with frequent relapses over a long period of time, and lasting until adulthood. It poses a great burden on families, social interactions and on quality of life. Factors influencing treatment outcome are largely unknown and published data are inconclusive. By identifying factors that influences treatment outcome, subgroups of patients with a poor outcome can be defined. Treatment of these patients can then be adjusted in order to improve outcome of treatment..

Primary study endpoint: number of patients treated successfully 6 months after start of treatment, and the improvement in Quality of Life at treatment success compared to a Dutch reference group of healthy children.

### Study objective

This study had two objectives:

1. which factors determine outcome of treatment of children with functional childhood constipation referred to the outpatient clinic of multidisciplinary treatment clinics in the Netherlands;
2. which factors can be related to an improvement in quality of life of children with functional childhood constipation referred to the outpatient clinic of multidisciplinary treatment teams in the Netherlands

### **Study design**

Prospective multicenter observational follow-up study. Total duration of the study: 24 months.

Recruitment period: 12 months, and follow-up period: 12 months. Total number of patients: 600.

Patients will be included from 4 multidisciplinary treatment teams in The Netherlands. Each participating center will include 200 patients.

### **Study burden and risks**

not applicable

## **Contacts**

### **Public**

Maasstadziekenhuis

Maasstadweg 21  
Rotterdam 3079 DZ  
NL

### **Scientific**

Maasstadziekenhuis

Maasstadweg 21  
Rotterdam 3079 DZ  
NL

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

### Inclusion criteria

Functional Childhood Constipation in children under the age of 4 (Rome III criteria (31):

Must include 1 month of at least 2 of the following in infants up to 4 years of age: 1. Two or fewer defecations per week, 2. at least 1 episode per week of incontinence after the acquisition of toileting skills, 3. History of excessive stool retention, 4. History of painful or hard bowel movements, 5. Presence of a large fecal mass in the rectum, 6. History of large-diameter stools that may obstruct the toilet\*.

Functional Childhood constipation in a child with a developmental age of at least 4 years with insufficient criteria of IBS (Rome III criteria):

Must include 2 or more of the following: 1. Two or fewer defecations per week, 2. at least one episode of fecal incontinence per week, 3. Stool retentive posturing, 4. Painful or hard bowel movements, 5. Large diameter stools that could obstruct the toilet, 6. Presence of a large fecal mass in the abdomen or rectum.

Age 0 - 16 years. Written informed consent by both parents and/or by patient in the age of 12-18 years.

### Exclusion criteria

Children with organic cause of constipation: Hirschsprung\*s disease, anorectal malformations, neuronal intestinal dysplasia, Spinal cord abnormalities, spinal cord trauma, neurofibromatosis, tethered cord, Hypothyroidism, diabetes mellitus, hypercalcemia, hypokalemia, vitamine D intoxication, Drug use: opioids, anticholinergic agents, antidepressants, Anorexia nervosa, sexual abuse, cystic fibrosis, dietary protein allergy.

Age above 18 years

## Study design

## Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-09-2016

Enrollment: 0

Type: Actual

## Ethics review

Approved WMO

Date: 27-08-2015

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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**

CCMO

**ID**

NL46945.101.13