Prevalence of signs of abuse in children with functional defecation disorders

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The aim of our study is to measure 1) the prevalence of signs of child abuse and neglect in children with functional defecation disorders, 2) whether signs of child abuse and neglect are more common in children with functional defecation disorders...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON44040

Source
ToetsingOnline

Brief title
Child abuse and functional defecation disorders

Condition

- Gastrointestinal motility and defaecation conditions
- Family issues

Synonym
constipation, functional defecation disorders

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Poeppoli

Intervention

Keyword: Abuse, Children, Constipation, FNRFI

Outcome measures

Primary outcome

Primary endpoint is the prevalence of evidence for abuse from history, physical examination or additional investigations in children with functional defecation disorders compared to the control group.

Secondary outcome

Secondary endpoint is the prevalence of stressful life events and traumatic symptoms in children with functional defecation disorders compared to the control group.

Study description

Background summary

Constipation en FNFRI are common problems in childhood. The pathophysiology of functional defecation disorders is probably multi-factorial and is largely unknown. From previous studies in children is known that maltreated children were more likely to have defecation disorders than healthy children. From studies in adults is known that adults suffering from functional gastrointestinal symptoms were more likely to have a history of child abuse or sexual abuse than adults suffering from organic gastrointestinal symptoms.

Study objective

The aim of our study is to measure 1) the prevalence of signs of child abuse and neglect in children with functional defecation disorders, 2) whether signs of child abuse and neglect are more common in children with functional defecation disorders than in children with functional abdominal pain and 3) whether stressful life events and traumatic symptoms are more common in children with functional defecation disorders than in children with functional abdominal pain.

Study design

A case-control study will be carried out in which the amount and size of stressful life events and signs of abuse in children with functional defecation disorders will be evaluated and compared with children with functional abdominal pain and healthy children. Patients with functional defecation disorders and patients with functional abdominal pain will be recruited from the outpatient clinic of the Emma Children*s Hospital. In these study groups, interviews and questionnaires will be completed in the outpatient clinic.

Study burden and risks

In theory, the study could be confronting for children who have experienced unpleasent events. However, we consider an early signaling and treatment of such a problem as important that we can justify further research. The investigations are not invasive and will be performed by trained professionals.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1) Patients aged 3-10 years old presenting at our specialized outpatient clinic with functional defecation disorders including functional constipation and functional non-retentive fecal incontinence (FNRFI) according to the ROME III criteria.
2) Patients aged 3-10 years old presenting at the outpatient clinic with functional abdominal pain according to the ROME III criteria.
3) School children aged 3-10 years old without gastro-intestinal complaints or chronic ilness

Exclusion criteria

1) General exclusion criteria:
-Parents with too little knowledge of the Dutch language to fill out the questionnaires.
-Parents with a too low intelligence quotient to fill out the questionnaires.
-Children with an intellectual disability who are unable to answer questions during the interview.
2) Index group:
-Children with constipation due to organic causes or surgical operations.
-Children with constipation due to medication.
3) Control group; functional abdominal pain:
-Children with abdominal pain due to organic causes or surgical operations.
-Children with abdominal pain due to medication.
4) Control group; healthy children:
-Children with gastro intestinal complaints (such as abdominal pain or constipation)
-Children with other chronic ilness

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2014
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL35893.018.11