Faecal calprotectin as a diagnostic test for IBD in children in primary care

Published: 22-10-2010
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To assess the (additional) diagnostic value of faecal calprotectin in children, age 4-18 years, with symptoms suggestive for IBD, in a primary and secondary/tertiary care setting.

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

Summary

ID

NL-OMON34153

Source
ToetsingOnline

Brief title
Calprotectin study

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds NutsOhra

Intervention

Keyword: child, diagnosis, inflammatory bowel disease, primary care

Outcome measures

Primary outcome

Sensitivity, specificity and ROC-curve of faecal calprotectin. Test results of faecal calprotectin will be compared to a diagnosis of IBD after 12 months follow-up. Outcome of care defined as optimal care, delay of diagnosis, and unnecessary endoscopy are secondary endpoints.

Secondary outcome

Health related quality of life

Study description

Background summary

Each year approximately 250 children in the Netherlands are diagnosed with inflammatory bowel disease (IBD: Crohn*s disease and ulcerative colitis). Symptoms of IBD can be atypical and overlap with symptoms of functional bowel disease. Diagnostic delay can have serious consequences, such as irreversible growth delay and negative effects on sexual development. Final diagnosis of IBD is based on invasive diagnostic tests, namely endoscopy under full anaesthesia. A simple and non-invasive screening test, suitable for children in primary care, that would both prevent diagnostic delay and unnecessary endoscopies, would be very helpful. Previous studies have shown that measuring faecal calprotectin is an easy, non-invasive and reliable test. However these studies were performed in highly selective patient groups in secondary and tertiary care settings not representing the care setting where this test is most needed, namely primary care.

Study objective

To assess the (additional) diagnostic value of faecal calprotectin in children, age 4-18 years, with symptoms suggestive for IBD, in a primary and secondary/tertiary care setting.

Study design

cohort study with a follow-up period of one year.

Study burden and risks

In this study we apply standard clinical practice, as we adhere to the CBO guideline *inflammatory bowel disease in children* . However, questionnaires and calprotectin measurements are not included in this guideline. Therefore, completing questionnaires and collecting a stool sample are regarded as an extra time investment. Benefits for participants of this study are being well monitored on symptoms, possible earlier detection of IBD. Good clinical care is guaranteed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1.Age 4-18 years
2.Diarrhoea >= 2 weeks or >= 2 episodes of diarrhoea in the past 6 months or recurrent abdominal pain (>= 2 episodes of abdominal pain in the past 6 months)
3.Informed consent

Exclusion criteria

1.Previously established diagnosis of chronic organic gastrointestinal disease
2.A complete evaluation in the past year for abdominal symptoms, including endoscopy
3.Chronic use of antibiotics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or oral corticosteroids.
4.Difficulty in understanding questionnaires due to cognitive impairment or language problems

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2011
Enrollment:	218
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2010

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL32660.042.10