Evaluation of small bowel activity in children suspected of inflammatory bowel disease

Published: 08-01-2009
Last updated: 07-05-2024

The goal of this study is to improve the diagnostic work-up of the small bowel in children suspected of IBD or diagnosed with CD and with suspicion of small bowel disease by comparing enteroscopy as gold standard to ultrasonography, Magnetic...

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

Summary

ID

NL-OMON32301

Source
ToetsingOnline

Brief title
Small bowel activity in children suspected of inflammatory bowel disease

Condition

- Gastrointestinal inflammatory conditions

Synonym
chronic inflammation of the gut, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: na goedkeuring van METC Erasmus MC zal om financiele ondersteuning verzocht worden bij gastrostart

Intervention

Keyword: Enteroscopy, MRI, Pediatric Crohn's disease, Wireless Capsule endoscopy

Outcome measures

Primary outcome

To detect disease activity in the small bowel of children suspected of IBD or diagnosed with CD with suspicion of small bowel disease.

Secondary outcome

1. To determine sensitivity and specificity of ultrasound, MRI and WCE compared to enteroscopy with histology in diagnosing IBD.

2. To determine sensitivity and specificity of ultrasound, MRI and WCE compared to enteroscopy with histology in detection of disease activity in the small bowel in IBD.

3. To determine the correlation between disease activity in the small bowel detected by ultrasound, MRI, WCE and enteroscopy with histology with clinical disease activity (PCDAI).

4. To determine the correlation between disease activity in the small bowel detected by ultrasound, MRI, WCE and enteroscopy with histology and laboratory findings (CRP, BSE).

5. To determine patient satisfaction, when undergoing ultrasound, MRI, WCE and enteroscopy.

6. To assess histology of the small bowel in the biopsies taken for the presence of Paneth cells, macrophages, dendritic cells, NKT, T and B lymphocytes and to test immunological cellular response.

Study description

Background summary

In pediatric CD, upper gastrointestinal tract involvement occurs frequently. The small bowel may also be involved, even though the terminal ileum is normal. In 2004, the ESPGHAN IBD working group developed the Porto criteria, to obtain uniformity in the work-up and criteria used for diagnosis. Every child suspected of IBD should undergo esophagogastroduodenoscopy (EGD), ileocolonoscopy (CS), both with biopsies and (in all cases except in definite ulcerative colitis) imaging of the small bowel with enteral contrast medium (x-enteroclysis). However, a drawback of imaging of the small bowel with enteral contrast medium is the ionizing radiation. Besides, sensitivity to detect findings consistent with CD is rather low. Alternative examinations for small bowel imaging are ultrasound, Magnetic Resonance Imaging (MRI), enteroscopy and wireless capsule endoscopy (WCE).

Study objective

The goal of this study is to improve the diagnostic work-up of the small bowel in children suspected of IBD or diagnosed with CD and with suspicion of small bowel disease by comparing enteroscopy as gold standard to ultrasonography, Magnetic Resonance Imaging (MRI), and WCE.

Study design

Prospective diagnostic study design.

Study burden and risks

Since the capsule can get stuck in patients with stenosis in the gut patients will undergo MRE and enteroscopy before WCE. Only after exclusion of stenosis on the MRE by the radiologist and during enteroscopy by the gastroenterologist, the video capsule will be inserted.
If there is any doubt that the videocapsule has passed the whole bowel, an X-ray of the abdomen will be performed after a few days (protocol pg. 7-8). The extra amount of time is minimal since the extra examinations are combined with the regular examinations.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 60
3000 CB Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 60
3000 CB Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients aged 8-18 years, suspected of IBD who would otherwise be scheduled to undergo an ileocolonoscopy and upper gastrointestinal endoscopy and x-enteroclysis or MRI to confirm or exclude this diagnosis.
Patients aged 8-18 years, diagnosed with CD with suspicion of small bowel disease who would otherwise be scheduled to undergo an ileocolonoscopy and upper gastrointestinal endoscopy and x-enteroclysis or MRI to evaluate small bowel disease.

Exclusion criteria

Pregnancy or lactation.
Inability to tolerate a 25 second breath-hold.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	08-01-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL21948.078.08