Developing the Pediatric MR Enterography-based Damage Index in Crohn's disease (pMEDIC) and the Pediatric Inflammatory Crohn's MRE Index (PICMI)

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

Summary

ID

NL-OMON40392

Source
ToetsingOnline

Brief title
ImageKids

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Shaare Zedek Medical Center
Source(s) of monetary or material Support: Abbott,Shaare Zedek Medical Center and Abbott,Shaare Zedek Medical Center Israel

Intervention

Keyword: Crohn's Disease, Inflammatory MRE Index, MRE-Based index, Pediatric

Outcome measures

Primary outcome

1. To develop an MRI-based index for assessment of intestinal damage in pediatric Crohn's disease (pMEDIC) , using robust psychometric and clinimetric methods

2. To develop an MRI-based index of radiologist reported signs of bowel inflammation/bowel inflammation in pediatric Crohn's disease (PICMI), using robust psychometric and clinimetric methods

3. To evaluate both indices for their clinimetric properties, including reliability, validity and responsiveness

Secondary outcome

1. To descibe the 18-month progression rate of intestinal damage in pediatric Crohn's disease, stratified by the different medications used, and disease duration at enrolment

2. To identify biological and clinical markers, predictive of intestinal damage

Study description

Background summary

Novel biologic therapies may be effective in achieving mucosal healing in Crohn's disease (CD), thereby reducing the long term risk for damage to the bowel, including stenosis and fistulas. However, at present there is no tool by which to measure intestinal damage and thus clinical trials of emerging novel therapies do not report the ability of the drug to change the natural history of the disease. In clinical practice, the rate of progression of damage has not been described in children, in part because accurate longitudinal reassessment of damage has not been possible. MR Enterography (MRE) can estimate both the intestinal inflammation and the degree of damage, but there is no validated scoring system for that modality. Currently, the IPNIC group is in the midst of developing a damage score in adults (called the Lemann score). Crohn's disease presents during childhood in up to 25% of cases, when it tends to be more extensive and may have a more aggressive disease course than in adults. Moreover, repeated endoscopic assessment and radiation-related imaging are considered less acceptable in children, notions that should be emphasized when developing scoring systems for children.

Study objective

The overall objectives of this proposal are to develop two indices capable of measuring intestinal damage, and, separately, inflammatory disease activity in Pediatric Crohn's disease by means of Magnetic Resonance Imaging with Enterography protocol (MRE).
The indices are aimed to be discriminative (at one point in time), evaluative (measuring damage progression over time) and predictive. The indices will be used as endpoint measures in clinical research and also in clinical practive to identify those who are at risk for rapid disease progression and surgery.

Study design

This is a longitudinal, prospective, multicenter, observational, cohort study in which a diversity of clinical parameters will be examined.
At inclusion in the study an MRE and gastroscopy and ileocolonoscopy wil be performed as standard patient care. In addition blood, urine and stool samples wil be collected and clinical parameters, growth and quality of life will be evaluated. The follow-up period will be 1.5 years, after which a repeated MRE will be performed. At 6 and 12 months after enrollment, a visit to the outpatient clinic will take place during which clinical and growth parameters will be collected and blood samples will be taken.
The management of patients will be dictated according to the discretion of the caring physician and not by this protocol.

Study burden and risks

The procedures involved in this study are almost all part of routine clinical care. The MRE scan and colonoscopy/upper endoscopy will not be different if

the child does not participate in this study. The added procedures for the study will be a quality of life survey and the second MRE after 18 months. For the MRE scan, a venous catheter must be placed, oral contrast must be taken and the child has to lie stil for about 45 minutes. This can be a burden for the patient. The quality of life survey will add a few minutes to 2 of the visits. The risk of all procedures are very low.

It is expected that the treatment of the individual patient can be optimized by using the new indices and by performing the second MRE scan. Nowadays, it is not current practice to perform a standard follow-up MRE in children with Crohn's disease without clinical complaints. Considering the risk of developing damage without actual complaints, however, this current practice may not be the best for the patient. The future use of the newly developed validated pMEDIC en PICMI scores based on MRE will make it unnessary to perform repeated colonoscopies, which is beneficial to the child.

Contacts

Public
Shaare Zedek Medical Center

Bayit Street 12
Jerusalem 91031
IL
Scientific
Shaare Zedek Medical Center

Bayit Street 12
Jerusalem 91031
IL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Children from age 5 (under 18 years of age) with established diagnosis of Crohn's disease involving any location, by the presence of accepted clinical, radiologic, endoscopic and histological criteria
- enrolment at the time of performing ileocolonoscopy and esophageal-gastroduodenoscopy (EGD) as part of clinical care for any reason
- Children will be enrolled at any phase of the disease (at diagnosis and thereafter as required clinically). In order to ensure enough subjects with intestinal damage and since damage is progressing over time, enrolment will be stratified based on disease duration. Enrolment for each stratum of disease duration will be closed after reaching the expected sample size
* 20% of enrolment children will be within 3 months of diagnosis
* 20% of children will be between 3 months and 2 years
* 20% will be 2 to 3 years
* 40% will have disease duration over 3 years
- Children may be enrolled in any disease activity state, Pediatric Crohn's Disease Activity Index (PCDAI) between 0 and 100.

Exclusion criteria

- Young children requiring anesthesia for the MRE because of lack of cooperation will be excluded (since the enteric contrast cannot be administered during the 2 hours before anesthesia and it is crucial that the contrast be given just prior the test)
- For the first 120 children only, subjects who are not expected to be available for 18 months follow-up, will be excluded (the last 120 subjects may be enrolled as they are not followed longitudinally)

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):	08-01-2014
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-11-2014
Application type:	Amendment
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
ClinicalTrials.gov	NCT01881490
CCMO	NL43209.078.13