Small bowel surveillance in patients with Peutz-Jeghers syndrome: comparing MR enteroclysis with double balloon enteroscopy.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON38353

Source
ToetsingOnline

Brief title
MRE versus DBE in Peutz-Jeghers syndrome.

Condition

- Gastrointestinal tract disorders congenital
- Benign neoplasms gastrointestinal

Synonym
Hamartomatous intestinal polyposis, polyps-and-spots syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Double balloon enteroscopy, MR enteroclysis, Peutz-Jeghers syndrome, Surveillance

Outcome measures

Primary outcome

Diagnostic yield of DBE and MRE, including number, location and size of polyps

in the small bowel of PJS patients.

Secondary outcome

- Quality of life and patients' appreciation of MRE and DBE;

- The need for DBE if MRE will be the primary surveillance method (for polyps >=

15 mm);

- Detection of significant extra-intestinal lesions with MRI;

- Total costs of both procedures;

- Complication rate of both procedures.

Study description

Background summary

Peutz-Jeghers syndrome (PJS) is a rare autosomal dominant inherited disorder, characterized by gastrointestinal hamartomas and mucocutaneous pigmentations. The incidence is low and has been estimated to be between 1:8,300 and 1:200,000 births. PJS is caused by germline mutations in the LKB1 gene. The predominant clinical features of PJS are the result of gastrointestinal polyposis, mainly of the small bowel, which can lead to abdominal pain, bleeding and intussusception already at a young age. The cumulative lifetime risk of intussusceptions is estimated to be 70%, and half of all patients have had an

intussusception at the age of 20 years. Furthermore, PJS is recognized as a cancer predisposition syndrome. Patients carry a high risk for the development of both gastrointestinal and extra-intestinal malignancies. The relative risk of developing any cancer lies between 10 and 18. For these reasons, PJS patients are offered surveillance Surveillance of the small bowel is mainly initiated to prevent complications (intussusceptions and bleeding) of small bowel polyps and the starting age is young. Furthermore, small bowel surveillance may prevent small bowel cancer or detect cancer at an earlier stage. Although several new techniques have been developed for the visualization of the small bowel, the optimal small bowel surveillance strategy for PJS has not been determined, since no controlled trials have been published on the best method and effectiveness.

Study objective

The aim of this prospective study is 1) to evaluate the diagnostic efficacy of DBE in comparison to MRE as surveillance technique of the small-bowel in PJS patients, 2) to analyze patient burden and quality of life with DBE and MRE, and 3) to evaluate the cost-effectiveness of DBE and MRE.

Study design

All patients with Peutz-Jeghers syndrome who are under surveillance at the Erasmus Medical Center in Rotterdam or the Academical Medical Center in Amsterdam, the Netherlands, are eligible for inclusion in this study. Included patients will undergo an MRE, followed by DBE via the oral route. The physician performing the DBE will be blinded for the MRE results. Number, location and size of polyps will be correlated. Polyps >= 15 mm encountered during DBE will be excised and analyzed histologically by a pathologist with gastrointestinal expertise. Furthermore, biopsies will be taken of lesions suspect for malignancy, as well as two biopsies of normal small intestine (duodenum, jejunum and if possible ileum). If a polyp >= 15 mm is seen with MRE, but is not detected during DBE, a new MRE will be performed one year after the first MRE, to confirm or exclude the presence of this polyp.
Using questionnaires before and after the inverstigations, quality of life and patient burden with the two different methods will be investigated.

Intervention

MR enteroclysis (MRE) uses magnetic resonance imaging (MRI), without the use of radiation, and enteroclysis. Contrast medium is infused in the intestine via a naso-enteric tube by which maximal luminal distension can be achieved to detect small bowel lesions. Double balloon endoscopy (DBE) is a new endoscopic technique. With the use of two balloons attached on the tip and distal end of the endoscope, the entire small bowel can be visualized. Furthermore, DBE can be used for therapeutic interventions during the same procedure, such as

polypectomy.

Study burden and risks

All included patients will undergo an MRE as well as a DBE. Both techniques are clinical practice for small bowel imaging and DBE is an adequate tool for polypectomy. Accurate documentation of small bowel polyps in Peutz-Jeghers patients and removal of large polyps can prevent complications of these polyps. To avoid deprivation of adequate treatment for participating patients, segmental unblinding of MRE results will be performed per small bowel segment during DBE.
During the study, patients will not be exposed to risks other than the known risks of MRE and DBE. Maximal three hospital visits are required for participating patients, including one visit to the Erasmus MC for DBE. Each investigation will take place in the outpatient clinic and will take 2 hours. Furthermore, patients are asked to fill out 4 questionnaires during the study period which will take approximately 15 minutes per questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients >= 18 years;
Patients who are willing and able to give informed consent.

Exclusion criteria

Inability to provide informed consent;
General contraindications to MR imaging (pacemaker or cardioversion device, claustrophobia, certain implanted metallic devices);
Patients with known contrast allergy;
Abdominal surgery in the 6 weeks prior to inclusion;
Pregnancy.

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):	27-07-2011
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Double balloon enteroscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-10-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-09-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-12-2012
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
CCMO	NL32747.078.10