Assessment of the performance of the new generation Pillcam colon capsule (PCCE 2) in Crohn's disease: an exploratory study.

Published: 01-02-2012
Last updated: 28-04-2024

In this study we will explore the examination with the second generation Pillcam capsule (PCCE 2) in patients with Crohn's disease. Crohn's patients with symptomps that need an endoscopy according to the treating physisian, will be asked...

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

Summary

ID

NL-OMON35999

Source
ToetsingOnline

Brief title
Pillcam study

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: GIVEN Imaging, Israël ,GIVEN imaging;Israël

Intervention

Keyword: Colonoscopy, Crohn's disease, Mucosal lesions, Pillcam video capsule

Outcome measures

Primary outcome

1. Diagnostic yield of PCCE 2 findings with attention to the type, size and location of lesions caused by Crohn's disease

2. Comparison of findings at PCCE 2 Pillcam recording and optical colonoscopy and validation of a Pillcam "inflammation score" using endoscopic scores as comparator

Secondary outcome

1. Safety and tolerability of the preparation procedure, the Pillcam examination and the optical colonoscopy

2. Determine inter-observer variability by serial readings of Pillcam recordings

3. Examine sensitivity and specificity of colonic Pillcam to detect mucosal healing in Crohn's patients before and after treatment with Infliximab or Adalimumab

4. Correlation of PCCE 2 findings and "inflammatory burden" measured by serum CRP and fecal Calprotectin

Study description

Background summary

The goals of treatment in Crohn's disease have evolved in recent years from symptom control to healing of mucosal lesions, usually visualized by

endoscopies. Potent treatment combinations, including anti-TNF agents and thiopurines, have made restoration of mucosal integrity attainable in a significant proportion of patients. Moreover, biologic therapies were shown to be more effective in patients that had visible ulcers on videoendoscopy than in patients without such lesions. This means that clinicians are recommended to check for the presence of ulcers before they embark on biologic therapy. Finally, endoscopic follow-up of treatment effects in Crohn's disease has entered routine practice.

However, endoscopic procedures are time consuming, unpleasant and expensive. Surrogate markers for the severity of inflammation such as faecal calprotectine are under investigation. Magnetic Resonance Enterocolonography (MRE) was shown to nicely parallel the severity of inflammation, but also this test is expensive and time consuming.

The development of a simple alternative to optical colonoscopy to assess mucosal inflammation in patients with Crohn's disease would therefore be of extreme importance. A reliable pill-cam examination is high on the priority list of potential options.

Study objective

In this study we will explore the examination with the second generation Pillcam capsule (PCCE 2) in patients with Crohn's disease. Crohn's patients with symptomps that need an endoscopy according to the treating physisian, will be asked to participate in this trial. They will both have a colonoscopy as a Pillcam examination in 1 day. The recordings of the PCCE 2 Pillcam will be compared with the findings of the colonoscopy.

Study design

An explorative open label study with 80 patients in 4 sites.

Study burden and risks

During the screening period an amount of 30 cc blood will be taken from the patient and the fecal Calprotectin will be measured once. Besides the patient will be asked to keep a diary during 7 days for the CDAI score.

Before both the Pillcam procedure and the colonoscopy the bowel needs to be clean. Therefore the patient needs to:
* follow a clear diet the day prior to the tests
* drink 2 litres Colopeg the evening before the tests
* drink 2 litres Colopeg the morning for the tests

After swallowing the PCCE 2 capsule, the patient will have to drink 30 cc of

Phosphosoda.

A cohort of 20 patients that are treated with anti-TNF, will be invited to undergo a second colonoscopy and Pillcam procedure after 8-12 weeks of treatment.

All participating patients will receive telephone calls from the study coordinator at 1 day, 1 week and 1 month after the procedures. The study coordinator will ask for Adverse Events.

A potential risk of the Pillcam examination is retention of the capsule in the bowel. In patients without (suspicion of) bowel stenosis this risk is negligible. When a stenosis is suspected, the patient will have to swallow a patency capsule, which has the same dimensions as the PCCE 2 capsule. When the patency capsule got stucked it will dissolcve within 36 hours after intake.

During colonoscopy patients will receive intra-venous sedative agents or a short comlete anaesthesia.
A colonoscopy is relative save. There is a small risk of complications (1 in 500 procedures), such as bleeding or perforation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Active Crohn's disease with CDAI > 150
* Elevated serum CRP (> 5 mg/l) and fecal calprotectin (> 200 ng/mg)
* Prior documentation of colonic involvement by Crohn's disease in at least one segment of the colon and more severe than only aphthous lesions
* Colonoscopy clinically indicated

Exclusion criteria

* Any contraindication for colonoscopy or colon capsule examination including swallowing disorders, severe congestive heart failure, renal insufficiency
* More than 1 resectional surgery for CD
* Subtotal or total colectomy
* Severely active fistulising disease
* Jejunal Crohn's disease
* HIgh suspicion of small bowel strictures
* Short bowel syndrome or stoma

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):	22-11-2011

Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Application type:	First submission
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	NL36332.018.11