The performance of PillCam colon capsule endoscopy in surveillance colonoscopy

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1. to compare the detection rate of colorectal polyps and cancer by CCE versus conventional colonoscopy in a surveillance population. 2. to investigate patients* acceptance, perceived burden and preference for surveillance test.

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON32619

Source
ToetsingOnline

Brief title
Performance of PillCam colon capsule endoscopy in surveillance colonoscopy

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

Synonym
colon polyps, colorectal adenomas

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal polyps, surveillance colonoscopy, video capsule endoscopy

Outcome measures

Primary outcome

Primary outcome measure:

The colorectal polyp miss-rate of CCE.

Secondary outcome

Secondary outcome measures:

1. Factors influencing the colorectal polyp miss-rate of CCE (bowel cleanliness

and characteristics of missed polyps).

2. Acceptance and burden of CCE

3. Patient preference regarding CCE or CC for surveillance.

Study description

Background summary

Colorectal cancer (CRC) is one of the most common cancers in western countries. Appropriate screening and surveillance could not only reduce the morbidity and mortality of CRC but also its incidence. Conventional colonoscopy (CC) is considered to be the best available method for the detection of adenomas and CRC. However, this is an invasive and costly procedure, associated with a procedural risk. The ideal test for screening and surveillance purposes should be safe, less invasive and cheaper than CC, and with a high diagnostic accuracy. Following the success of the small bowel capsule endoscopy, colon capsule endoscopy (CCE) might be an attractive alternative for colon screening and surveillance.

Study objective

1. to compare the detection rate of colorectal polyps and cancer by CCE versus conventional colonoscopy in a surveillance
population.

2. to investigate patients* acceptance, perceived burden and preference for surveillance test.

Study design

Patients with a personal or family history of colorectal polyps or cancer scheduled for a surveillance colonoscopy will first undergo CCE, followed by a CC, within approximately one week. In both methods all detected polyps will be classified with respect to segmental location, size, morphology and macroscopic aspect. The conventional colonoscopy will be performed with segmental unblinding for the results of the CCE. Conventional colonoscopy in combination with histology will be used as reference standard. The determination of true-positive polyps for CCE will be done by an independent physician, experienced in capsule endoscopy, comparing the documented characteristics, pictures and (if needed) videos of all detected polyps during both CCE and CC.

Study burden and risks

A risk of videocapsule endoscopy is retention of the capsule. In patients without (suspected) intestinal stenosis or obstruction this risk is negligible. To date no adverse events were reported with CCE.

For Voor colon capsule endoscopie is net als bij de conventionele colonoscopie darmvoorbereiding noodzakelijk met laxeermiddelen en een aangepast dieet. Patienten die meedoen aan dit onderzoek zullen dit twee keer moeten ondergaan, zowel voor de colon capsule endoscopie als voor de conventionele colonoscopie.

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 with a personal history of colorectal adenomas or CRC or a family history for CRC, scheduled for surveillance colonoscopy at the endoscopy department of the Academic Medical Center or the Slotervaart Hospital.

Exclusion criteria

Age younger than 18 years
Personal history of IBD
Polyposis syndromes
Known colorectal polyps, not removed at prior endoscopy
Dysphagia
Known or suspected intestinal obstruction
Surgical intestinal anastomosis
Inability to understand patient information and/ or give informed consent
Renal insufficiency
Congestive heart failure
Pacemaker or implantable cardiac defibrillator
No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2008
Enrollment:	170
Type:	Anticipated

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	NL24178.018.08