COLON CANCER SCREENING BY MEANS OF COLON CAPSULE ENDOSCOPY - A pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON45208

Source
ToetsingOnline

Brief title
pilot CRC-screening by colon capsule endoscopy

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
adenomas, colorectal polyps/bowel cancer

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: colon capsule endoscopy, Colorectal cancer, pilot, Screening

Outcome measures

Primary outcome

The pilot study will focus completely on testing of the quality of the CCE procedure as intended in the screening trial. The main study parameters are feasibility and logistical shortcomings, efficacy of bowel preparation and understandability of information material.

Secondary outcome

n.a.

Study description

Background summary

Colorectal cancer (CRC) is one of the most common malignancies both in men and women, and accounts for the second cause of cancer-related death in the Netherlands. The high incidence of the disease, the recognizable precursor, the long preclinical stage, and the fact that the intensity of treatment and the risk of death strongly correlate with disease stage all make CRC very suitable for screening. Long-term randomized prospective trials both based on fecal occult blood testing (FOBT) as well as sigmoidoscopy showed that screening indeed reduces CRC-related mortality, and depending on the method also CRC incidence. Screening programs in other countries as far as implemented by now are generally based on FOBT screening, while some use sigmoidoscopy or opportunistic colonoscopy and CT-Colonoscopy screening. The shortcomings of these approaches are insufficient population coverage, and insufficient yield. Colon capsule endoscopy (CCE) appears to be a promising new modality for colonic evaluation. CCE can be the long-expected next generation screening modality, if a high uptake and diagnostic yield are confirmed in primary population screening. The results of this pilot study will serve as the basis for a larger population-based trial to accurately determine the position of CCE as primary screening tool, as well determination of the required colonoscopy capacity resulting from primary CCE screening.

Study objective

The pilot study will focus completely on testing of the quality of the CCE procedure as intended in the screening trial. The main study parameters are feasibility and logistical shortcomings, efficacy of bowel preparation and understandability of information material.

Study design

Participants are invited to capsule endoscopy screening using the Pillcam colon 2/2L (Given Imaging ltd. Israel) before colonoscopy.

Intervention

Participants are invited to capsule endoscopy screening using the Pillcam colon 2/2L (Given Imaging ltd. Israel). Colon cleansing consists of a tablet Bisacodyl 5 mg (Centrafarm BV) at bedtime 2 days before CCE. Subsequently all participants will start a liquid diet the day before CCE and will receive 2 liter of polyethylene electrolyte glycol solution (Moviprep; Norgine, Amsterdam, The Netherlands) and 2 liter transparent fluid, split-dose. Booster during CCE procedure consists of additional 250ml Eziclen boost and an optional 250ml Eziclen boost, each followed by about 0.5 liter of clear liquids. The second administration is an optional booster, 3 hours after the first booster which participants will only be instructed to drink in case the capsule has not already been excreted. After bowel preparation and capsule endoscopy, patients subsequently will have colonoscopy according to regular procedure.
Participants are asked twice to complete a questionnaire about the expected and perceived burden; it will take 5-10 minutes to complete one questionnaire.

Study burden and risks

Potential adverse events associated with the use of Pillcam colon 2/2L may include obstruction or retention of the capsule. Capsule retentions can be resolved by either laxative ingestion or removal of the capsule during colonoscopy or in very rare cases surgery.
The procedure involves laxatives and prokinetic agents. See the SPC-texts of metoclopramide, moviprep or bisacodyl for possible adverse events.

It is made clear that participation is completely voluntary. There are no individual benefits; participant feedback provides information for improving the quality of the CCE procedure as intended in the screening trial.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

s Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

s Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All consecutive ambulatory patients referred for a colonoscopy at the Gastroenterology and Hepatology Department of the Erasmus MC because of a suspicion of colorectal polyps or colorectal cancer or a positive iFOBT after participation in a FOBT-based CRC screening trial will be eligible for participation.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Inability or refusal to provide informed consent.
- Persons with a severe or terminal disease with a life-expectancy of less than 5 years.

- An allergy or any other known contraindication to the medication used in the study, including:
- Renal failure, eGFR <60 ml/min/1.73m2
- Congestive heart failure NYHA class III or IV.
- Dysphagia or other swallowing disorder which makes it impossible to swallow the capsule.
- Personal history of gastrointestinal surgery other than uncomplicated procedures that would be unlikely to lead to bowel obstruction based on the clinical judgment of the investigator.
- Cardiac pacemakers or other implanted electro-medical equipment.
- An MRI scheduled within 14 days after ingestion of the capsule.
- Although pregnancy is not likely in this cohort, pregnant women are also excluded.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2013
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	PillCam Colon 2/2L capsule
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-11-2013
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-11-2016
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	NL44021.078.13