COlon Capsule Endoscopy as an AlterNative for CT-colonography in Colorectal Cancer Screening

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

Summary

ID

NL-OMON55511

Source
ToetsingOnline

Brief title
The OCEAN Trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer, colorectal neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Medtronic B.V.,MLDS subsidie;Medtronic

Intervention

Keyword: "Capsule Endoscopy"[Mesh], "Colorectal Neoplasms"[Mesh], "Early Detection of Cancer" [Mesh]

Outcome measures

Primary outcome

To evaluate the applicability of Colon Capsule Endoscopy in patients screened

positive with a fecal immunochemical test (FIT) who have a contra-indication

for subsequent colonoscopy, who are unwilling to undergo colonoscopy or who had

a prior incomplete colonoscopy within the Dutch colorectal cancer screening

setting by:

a. Evaluating diagnostic yield of Colon Capsule endoscopy

b. Evaluating the participation rate of the Colon Capsule endoscopy

c. Evaluating the expected- and perceived burden of Colon Capsule Endoscopy.

d. Evaluating the workability for the staff of Colon Capsule Endoscopy.

e. Evaluating the interobserver variability between different reviewers of

Colon Capsule Endoscopy.

Secondary outcome

n.a.

Study description

Background summary

Since 2014 a nationwide fecal immunochemical test (FIT) based CRC screening programme has started in the Netherlands. All people between 55-75 years old are invited to participate. In case of a positive FIT, subjects are referred to undergo a colonoscopy. However, almost 25% of the participants with a positive FIT outcome do not undergo a subsequent colonoscopy. Colonoscopy is an invasive

procedure for which sedation is needed, which makes it not possible for everyone due to contra-indications or patient preferences, and if it is possible, it is not always possible to complete the whole procedure. In these cases participants are referred to undergo CT-colonography, a noninvasive procedure for which no sedation is needed. However, the sensitivity of CT-colonography is significantly lower than with colonoscopy, especially for smaller polyps. On top of that, CT-colonography may have harms resulting from low-dose ionizing radiation exposure or unintentional identification of extracolonic findings. Colon capsule endoscopy (CCE) is a noninvasive technique to explore the colon without the need for sedation or radiation exposure. On top of that, after taking in the colon capsule, the patient can go home again. The sensitivity of CCE is almost similar to colonoscopy and superior to CT-colonography, especially for smaller polyps. CCE has also shown to be effective for detection of additional relevant findings after incomplete colonoscopies. Several studies have shown that CCE could potentially increase participation rates among people who decline screening colonoscopy. Despite all this, CCE is still not a part of the regular screening programme.

Study objective

The aim of this study will be to evaluate the applicability of using CCE in the Dutch colorectal cancer screening programme in participants with positive FIT outcomes who have contra-indications for subsequent colonoscopy, who have a prior incomplete colonoscopy or who are unwilling to undergo colonoscopy. The diagnostic yield, participation rate, expected- and perceived burden of using CCE for the patient, the workability of CCE for the staff and the interobserver variability between different reviewers will be evaluated.

Study design

This study is a prospective, observational cohort study. It is initiated at the Erasmus MC and has a future perspective to extend to a multicenter study. All screenees tested FIT positive within the nationwide colorectal cancer screening programme who have a contra-indication for subsequent colonoscopy, who are unwilling to undergo colonoscopy or who had a prior incomplete colonoscopy are invited to participate in this study.
Study information will be given during the intake and the patient information folder will be handed out together with a notification card. When willing to participate, the subject sends a positive notification card to the research team after which the colon capsule endoscopy will be planned. The informed consent form will be signed by the participant as well as the researcher on the day of the capsule endoscopy.
For this study, the PillCam® Colon 2 capsule (Medtronic ltd, Brussels) will be used. The day prior to the procedure bowel preparation and an adjusted diet should take place. Analysing the CCE findings will be done by either a specialised company or a qualified specialist, depending on the preferences of

the participating hospital. The hospital can also choose for members of their personell to get training in reviewing the CCE images. All CCE videos will be double checked by the EMC team with expertise in CCE reading.
When there are no findings, subjects will be re-invited for FIT within the national CRC screening programme in 10 years. In case of polyps smaller then 6mm, patients will be advised a surveillance CT-colonography in 3 years. In case of polyps over 6 mm or colorectal cancer, patients are referred for colonoscopy. These guidelines are in line with the currently used guideline for CT-colonography.
Patients expected- and perceived burden will be evaluated by using 2 questionnaires prior and after the CCE procedure.
The workability of CCE for the staff will be evaluated by using a questionnaire.

Study burden and risks

Colon capsule endoscopy provides a less invasive procedure than colonoscopy to screen for colorectal disease in the national screening programme without the need for sedation, insufflation, exposure to radiation or admission to a hospital. Colon capsule endoscopy in a safe procedure. The Pillcam Colon 2 capsule is CE-approved. It has a FDA-approval for the use after an incomplete colonoscopy. In Europe, colon capsule endoscopy is specifically approved as an option to screen for colorectal cancer in average risk patients or high risk patients with contra-indications for colonoscopy or who refuse colonoscopy (ESGE-guidelines). Complications were almost all attributed to bowel cleansing and/or the result of subsequent colonoscopy. Some case reports raised the possibility of capsule aspiration or retention in a diverticulum. There are some contra-indications for CCE in which the procedure could be potentially less safe, including obstructive symptoms, suspected intestinal strictures, pregnancy and implantable cardiac devices. This is the reason why these patient groups are included in our exclusion criteria.

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

1. Participation in the Dutch national CRC screening programme
2. Positive result on FIT screening
3. Contra-indications to undergo colonoscopy or sedation OR
4. Not willing to undergo colonoscopy OR
5. Prior incomplete colonoscopy

Exclusion criteria

1. Inability or refusal to provide informed consent
2. Persons with a severe or terminal disease with a life-expectancy of less than 5 years
3. An allergy or any other known contraindication to the medication used in this study
4. Renal failure, eGFR <30 ml/min/1.73m2
5. Congestive heart failure NYHA class III or IV
6. Dysphagia or other swallowing disorder which makes it impossible to swallow the capsule
7. High risk of capsule retention: IBD, 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
8. Cardiac pacemakers or other implanted electro-medical equipment
9. An MRI scheduled within 14 days after ingestion of the capsule
10. Patients with diagnosed or suspected Congenital Long QT Syndrome
11. Patients with high risk concomitant use of drugs that prolong the QT

interval. The risk should be based on the concerning medication in combination with the dosages and should be evaluated based on the clinical judgement of the investigator.
12. Patients with manifest hyperthyroidism
13. Patients with an allergy or hypersensitivity for iodinated agents

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2020
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Pillcam Colon 2L videocapsule endoscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-06-2020

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-05-2021
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	NL69272.078.19
Other	NTR;NL8795