Discovery: Pentax* Computer-aided Detection to Improve Adenoma Detection in a Real-time Setting - The Discovery II Study. A randomized clinical trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational invasive

Summary

ID

NL-OMON49600

Source
ToetsingOnline

Brief title
The Discovery II Study

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign

Synonym
Colorectal adenomas and polyps

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Pentax Medical Europe

Intervention

Keyword: Adenoma, Colonoscopy, Computer Aided Detection (CADe), Polyp

Outcome measures

Primary outcome

The main study parameter is the adenoma detection rate (ADR), which calculated as the number of patients in whom at least one adenoma is detected during the colonoscopy procedure, divided by the total number of patients that underwent the colonoscopy procedure (e.g. PCSC or CC).

Secondary outcome

- The PDR (calculated as the number of patients in whom at least one polyp is detected during the colonoscopy procedure, divided by the total number of patients that underwent the colonoscopy procedure (e.g. PCSC or CC);

- The mean number of adenomas detected per patient;

- The mean number of polyps detected per patient;

- The number of sessile serrated lesions;

- The number of advanced adenomas (i.e. adenomas >= 10 mm and/or harbouring a villous component and/or containing HGD;

- Size of the lesion;

o 0-5 mm, 6-10 mm, 10-20 mm, >20 mm

- Location of the lesion;

o Caecum, ascending, transverse, descending, sigmoid, rectum

- Morphological characteristics of the lesion using the Paris classification;

o Ip, Is, IIa, IIb, IIc, III

- Histopathological characteristics of the lesion according to the Vienna classification;

- The ADR of the first 20% of patients scoped by each endoscopist will be compared with the final 20% of patients in each arm to identify any changes in ADR throughout the trial;

- Bowel cleansing levels using the BBPS;

- Procedure times with both techniques (i.e. total procedure time, mean polypectomy time and withdrawal time);

- (Severe) adverse events up to 30 days post-procedure;

- Post-colonoscopy surveillance intervals when applying European and US surveillance guidelines;

- The number of false positives;

- The reason why a notification is assessed as false positive by the endoscopist (i.e. bubbles, fecal material, etc.);

- The number of false negatives.

Other study parameters

- Gender

- Age

- Smoking status

- BMI

- Type of endoscope used

- Family history of (colorectal) cancer

Study description

Background summary

Colorectal cancer (CRC) is the third most commonly diagnosed malignancy and the fourth leading cause of death in the Western world. CRC usually develops from focal changes within benign, precancerous polyps. Colonoscopy aims to early detect and remove these precancerous polyps. Although colonoscopy is generally considered to be the most accurate screening modality, a substantial number of polyps are still missed. Two meta-analysis showed pooled miss rates for polyps of any size of 22-26%, an adenoma miss rate (AMR) of 26% for diminutive polyps (1-5mm) and an AMR of 27% for serrated polyps. Missed lesions may have the possibility to develop into cancer and it is thought that at least 50% of all interval carcinomas (iCRCs; defined as a cancer diagnosed between screening and post-screening surveillance colonoscopies) arise from missed lesions during colonoscopy. In recent years, a new solution to human error in detecting polyps has been developed; computer-aided detection (CADe) systems. CADe systems use deep learning to improve polyp and adenoma detection in a more consistent and reliable way. In the past years, several CADe systems have been developed. Albeit performance of these systems on offline videos and images seems promising, evidence on the ability during real-time clinical practice is lacking. Recently Pentax Medical has developed a CADe system, named *Discovery*. Pre-clinical studies have shown a 90% and 75.2% sensitivity and specificity, respectively, with an area under curve (AUC) of 91% for polyp detection (unpublished data). We hypothesize that the use of the Pentax Discovery system is feasible and safe.

Study objective

The primary objective of the study is to compare the ADR between PCSC and CC in patients referred for diagnostic, screening (non-iFOBT based) or surveillance colonoscopy.

Secondary objectives are the following:
- To compare the polyp detection rate (PDR);
- To compare the mean number of adenomas per patient detected;
- To compare the mean number of polyps per patient detected;
- To compare the number of sessile serrated lesions (SSLs) detected;
- To compare the number of advanced adenomas (i.e. adenomas >= 10 mm and/or harbouring a villous component and/or containing high grade dysplasia (HGD)) detected;
- To compare detected colon lesions for size, location (per colon segment and

in relation to colonic folds), morphology (using the Paris classification) and histopathological characteristics (using the Vienna classification);
- To compare the ADR of the first 20% of patients scoped by each endoscopist with the last 20% of patients in each arm to identify any changes in ADR throughout the trial (i.e. as part of a learning effect);
- To compare bowel cleansing levels using the Boston Bowel Preparation Scale (BBPS);
- To compare procedure times for both techniques (i.e. total procedure time, mean polypectomy time and withdrawal time in each colonic segment);
- To compare (severe) adverse events (S(AE)s) up to 30 days post-procedure;
- To compare post-colonoscopy surveillance intervals applying European and US surveillance guidelines;
- To assess the number of false positives by the PCS (defined as the number of times the system highlights an unsuspected area (as assessed by the endoscopist) >3 seconds)
- To assess the reason why a notification by the PCS is assessed as false positive by the endoscopist (i.e. due to bubbles, fecal material, etc.);
- To assess the number of false negatives by the PCS (defined as the number of times the system does not highlight an unsuspected area (as assessed by the endoscopist) <3 seconds)

Study design

Randomized, two arm colonoscopy trial, including 560 patients.

Study burden and risks

Patients will be enrolled for a period of 30 days, starting at the day of the procedure and ending after 30 days of follow up. It is likely that the Pentax CADe system will lead to the detection of more (adenomatous) polyps and thereby resulting in more polypectomies, therefore participation in the study might lead to a longer procedure time and more adverse events, especially the risk of intraprocedural or delayed bleeding. Nonetheless, the risk of intraprocedural or delayed bleeding is estimated to be low, i.e. 1.8% and <=0.1%, respectively. Most bleedings can be treated during the same, or an additional colonoscopy, procedure. The removal of additional polyps that are detected by the CADe system might have a beneficial effect on the morbidity and mortality resulting from colorectal carcinoma, depending on the type of polyp that is removed during the procedure. The follow-up of the procedure (e.g. the number of hospital visits) will take place according to local guidelines.

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

- >= 18 years
- Referred and scheduled for diagnostic, screening (non-iFOBT based) or surveillance colonoscopy.

Exclusion criteria

- Known colorectal tumor or polyp on referral;
- Referral for a therapeutic procedure (i.e. endoscopic mucosal resection, intervention for lower gastro-intestinal bleeding, etc.);
- Inadequately corrected anticoagulation disorders or anticoagulation medication use;
- American Society of Anesthesiologists (ASA) score >= 3;
- Known or suspected inflammatory bowel disease;
- Inability to provide informed consent.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-05-2021
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Computer Aided Detection (CADe) System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL73127.091.20

Study results

Results posted: 24-09-2024

First publication
16-05-2024