Discovery II Study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22821

Source
NTR

Brief title
Discovery II

Health condition

Colorectal carcinoma, colorectal polyps, colorectal adenomas

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Pentax Medical Europe

Intervention

Outcome measures

Primary outcome

Adenoma detection rate (ADR)

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; 0-5 mm, 6-10 mm, 10-20 mm, >20 mm
- Location of the lesion; Caecum, ascending, transverse, descending, sigmoid, rectum
- Morphological characteristics of the lesion using the Paris classification18; Ip, Is, IIa, IIb, IIc, III
- Histopathological characteristics of the lesion according to the Vienna classification19;
- 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 BBPS20;
- 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.

Study description

Background summary

Rationale
Adenoma detection rate (ADR) is known to be inversely correlated with the incidence of colorectal cancer (CRC). Multiple factors are considered to have a negative impact on the adenoma detection rate (ADR), one of them being human error. In recent years, a new solution to the human error for detecting adenomas has been developed; computer-aided detection (CADe) systems. Albeit performance of these systems on offline images and videos seems promising, evidence on the ability during real-time clinical practice is lacking. Recently, Pentax introduced a novel CADe-system, named “Discovery”.

Objective
The primary objective of the present study is to compare the adenoma detection rate (ADR) between Pentax CADe system assisted colonoscopy and conventional colonoscopy. The secondary outcomes are (among others) polyp detection rate and total number of adenomas and polyps detected during colonoscopy.

Study design
Randomized, multicenter, two arm colonoscopy trial, including 560 patients.

Study population
Patients aged ≥ 18 years, referred and scheduled for diagnostic, screening (non-iFOBT based) or surveillance colonoscopy.

Main study parameter
The main study parameter is the ADR. Other study parameters will include the polyp detection rate, mean number of adenomas and polyps.

Nature and extent of the burden and risks associated with participation, benefit and groups relatedness
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 use of the Pentax CADe system will result in the detection of more (adenomatous) polyps and thereby in the necessity of performing more polypectomies. Therefore, participation in the study might lead to a longer procedure time and more adverse events, especially an increased 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, and endoscopic modalities are available to treat post-polypectomy bleedings. 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 after the procedure (e.g. the number of hospital visits and follow-up colonoscopies) will be performed according to local and (inter)national guidelines.

Study objective

The adenoma detection rate (ADR) will be higher in the intervention group compared to the control group.

Study design

Findings during colonoscopy, SAE's up to 30 days post-colonoscopy

Intervention

Usage of Pentax Discovery Computer Aided Detection System.

Contacts

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Scientific

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Eligibility criteria

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 resection, intervention for lower gastro-intestinal bleeding, etc.);
- Inadequately corrected anticoagulation disorders or anticoagulation medication use;
- American Society of Anesthesiologists (ASA) score 3;
- Inability to provide informed consent;
- Known or suspected inflammatory bowel disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	04-01-2021
Enrollment:	560
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	21-12-2020
Application type:	First submission

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
NTR-new	NL9135
Other	CMO Arnhem-Nijmegen : 2020-6266

Study results