Synergistic effect of G-Eye balloon for behind the folds visualization with artificial intelligence assisted polyp detection (Discovery system) on adenoma detection rate. *Discovery III study*

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

Summary

ID

NL-OMON51795

Source
ToetsingOnline

Brief title
Discovery III study

Condition

- Benign neoplasms gastrointestinal

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, Colorectal Carcinoma, Computer Aided Detection (CADe)

Outcome measures

Primary outcome

The main study parameter is the ADR, 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.

Secondary outcome

- AADR, calculated as the number of patients in whom at least one advanced adenoma is detected during the colonoscopy procedure, divided by the total number of patients that underwent the colonoscopy procedure
- 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
- TSDR, calculated as the number of patients in whom at least one SSL is detected during the colonoscopy procedure, divided by the total number of patients that underwent the colonoscopy procedure
- Indication specific ADR, i.e., ADR specific for screening, diagnostic, or surveillance
- Mean number of adenomas detected per patient

- Mean number of polyps detected per patient

- Number of sessile serrated lesions

- Number of advanced adenomas (adenomas >= 10 mm and/or with a villous component and/or with HGD

- Size of the lesion subdivided in categories 0-5 mm, 6-10 mm, 10-20 mm, >20 mm

- Location of the lesion: cecum, ascending colon, transverse colon, descending colon, sigmoid, rectum;

- Morphological characteristics of the lesion using the Paris classification (Ip, Is, IIa, IIb, IIc, III)

- Histopathological characteristics of the lesion according to the Vienna classification

- ADR of the first 20% of patients that have undergone colonoscopy 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 using the BBPS

- Cecal intubation rate (CIR)

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

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

- SAEs will be subcategorized into colonoscopy related, cardiac (cardiac ischemia, heart failure, arrhythmia, other) pulmonary (exacerbation COPD, infectious, other), neurological (stroke, cerebrovascular accident, bleeding, other), and other (surgical interventions etc.)

- GCS score and analgesia use

- Post-colonoscopy surveillance intervals when applying European and US

surveillance guidelines

Study description

Background summary

Colonoscopy is the gold standard for CRC screening. The adenoma detection rate (ADR) is the most important quality parameter for colonoscopy, because of its inverse association with the risk of interval CRC. Yet, the adenoma miss rate (AMR) in conventional colonoscopy is reported in meta-analyses to vary between 22-26%. The diagnostic accuracy of colonoscopy highly depends on the quality of inspection of the colonic mucosa during the procedure. To increase the adenoma detection rate (ADR), new polyp/adenoma detection systems based on artificial intelligence (AI) have been developed, i.e., computer assisted detection (CADe). However, these systems still depend on the ability of the endoscopist to adequately visualize the complete colonic mucosa, especially to detect smaller and more subtle lesions. Therefore, we hypothesize that ADR can further be improved by combining a CADe system, the Discovery system, with a behind the fold (BTF) visualization technique, the G-Eye.

Study objective

The primary objective of this study is to compare the effect on ADR of combining balloon-assisted and CADe assisted colonoscopy, compared to CADe assisted colonoscopy only.

Secondary objectives are to compare the effect of adding balloon-assisted to a CADe-assisted colonoscopy on:
- Advanced adenoma detection rate (AADR). Adenomas are classified as advanced with a size >=10mm and/or a (tubulo)villous histology and/or high-grade dysplasia (HGD);
- Polyp detection rate (PDR);
- Sessile serrated lesion (SSL) detection rate (SDR);
- Mean number of polyps per patient;
- Size, morphology, and histopathology of lesions found.;
- Procedure time, including total procedure time, mean polypectomy time, withdrawal time;
- Bowel cleaning using the Boston Bowel Preparation Scale (BBPS);
- Cecal intubation rate;
- Patient comfort, using the Gloucester Comfort Scale (GCS) and sedation and analgesia use;
- Safety, in terms of (severe) adverse events up to 30 days post-procedure;

- Interoperator variability and learning curve;
- Post-colonoscopy surveillance intervals using European (ESGE) and US (ASGE) surveillance guidelines;

Study design

International multicenter prospective interventional cohort, compared with a cohort from the Discovery II study (NL73127.091.20, trial code NL9135). All subjects will be undergoing colonoscopy with a combined BFT and CADe assisted approach. Outcomes will be corrected for confounders using regression modeling.

Study burden and risks

Eligible patients who are scheduled for surveillance colonoscopy will undergo one BFT and CADe assisted colonoscopy. There will be no burden for participants regarding the colonoscopy procedure. Colonoscopy is a commonly performed procedure, and the overall serious adverse event rate is low with an estimated risk 2.8 per 1000 colonoscopies. The risk of experiencing a (serious) adverse event with G-Eye and Discovery guided colonoscopy is believed to be equivalent to conventional colonoscopy. The benefit for patients is a higher likelihood of lesion detection during colonoscopy.

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

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

Exclusion criteria

- Known polyp or tumor upon referral
- Therapeutic procedure (e.g., endoscopic mucosal resection)
- Prior surgical resection of any portion of the colon
- American Society of Anesthesiologists score of >=3
- Inadequately corrected anticoagulation disorder or anticoagulation medication use
- Inflammatory bowel disease (IBD)
- inability to provide informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-03-2022
Enrollment:	70

Type:	Actual

Medical products/devices used

Generic name:	G-Eye balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-01-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-05-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-08-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-08-2024
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	NL80004.091.21