Discovery: Pentax* Computer-aided Detection to Improve Adenoma Detection in a Real-time Setting - The Discovery I Study

Published: 14-07-2020
Last updated: 08-04-2024

The primary objective of this study is to evaluate the feasibility of the Pentax CADe-system during colonoscopy procedures in terms of the polyp detection rate (PDR). We hypothesize that the use of the Pentax CADe-system is feasible and enables...

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

Summary

ID

NL-OMON50010

Source
ToetsingOnline

Brief title
The Discovery I 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 PDR, defined as the number of colonoscopies in

which >=1 polyp is detected divided by the total number of colonoscopies.

Secondary outcome

- Mean number of polyps

- Mean number of adenomas

- ADR

- Polyp location

Caecum, ascending, transverse, descending, sigmoid, rectum

- Polyp shape according to the Paris classification

Ip, Is, IIa, IIb, IIc, III

- Polyp size

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

- Polyp type

Adenoma, sessile serrated lesion, hyperplastic polyp

- Withdrawal time (minutes)

- Procedure time (minutes)

- Boston Bowel Preparation Scale (3-9)

- (Serious) Adverse events

- Endoscopists* evaluation of:

Number of polyps that would have been missed without the CADe-system;

- Endoscopists* subjective evaluation on a Likert scale of:

User friendliness

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 this study is to evaluate the feasibility of the Pentax CADe-system during colonoscopy procedures in terms of the polyp detection rate (PDR). We hypothesize that the use of the Pentax CADe-system is feasible and enables detection of colorectal polyps with a PDR of >=0.37, corresponding to an ADR of >=0.25, in accordance to current guidelines.

Secondary objectives are the following:
- To assess which type and size of polyps are detected by the Pentax CADe-system
- To assess whether quality indicators for colonoscopy (e.g. ADR, withdrawal time) are affected by the Pentax CADe-system
- To assess the safety of the Pentax CADe-system
- To evaluate the endoscopists* experience using the Pentax CADe-system
- To assess the diagnostic performance of the CADe System for detecting colorectal adenoma (e.g. sensitivity, specificity, false positive rate)
- To assess the number of polyps that are primarily detected by the system

Study design

Prospective, multicenter cohort study including a total of 90 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

Public
Radboud Universitair Medisch Centrum

Geert Grootplein Zuid 10
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grootplein Zuid 10
Nijmegen 6500 HB
NL

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 either 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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2020
Enrollment:	30
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)

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	NL73099.091.20