Effect of a computer-aided detection system (CAD EYE) on adenoma detection in patients with Lynch syndrome: an international, multicenter parallel randomized controlled trial

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To compare adenoma detection rates of colonoscopy with and without a CADe system during surveillance colonoscopy of patients with Lynch syndrome.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON51017

Source
ToetsingOnline

Brief title
CAD EYE LYNCH

Condition

- Gastrointestinal neoplasms benign

Synonym
Lynch syndrom, polyps

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Fujifilm

Intervention

Keyword: Colonoscopy, Lynch syndrome, Polyp detection, RCT

Outcome measures

Primary outcome

Adenoma detection rate of colonoscopy with CADe system versus colonoscopy without CADe system

Secondary outcome

- The difference in polyp detection rate between colonoscopy with and without CADe system

- The difference in mean number of polyps between colonoscopy with and without CADe system

- The difference in mean number of adenomas between colonoscopy with and without CADe system

- The difference in mean number of serrated polyps between colonoscopy with and without CADe system

- The difference in proximal serrated polyp detection rate between colonoscopy with and without CADe system

- The difference in mean number of proximal serrated polyps between colonoscopy with and without CADe system

- The mean duration of both endoscopic procedures with and without CADe system: time for inspection and time for performing endoscopic resection

- False positive detections of the CADe system: a flashing alert (whereby a detection box, circle and/or sound signal appears then disappears) and consistent false detection (whereby the CADe system consistently identifies a non-polyp structure as a polyp but the endoscopist disagrees at close observation)

Study description

Background summary

Colonoscopy with computer-aided detection (CADe) has been shown to improve detection of colon polyps and adenomas in the average-risk population during randomized trials. Patients with Lynch syndrome have accelerated carcinogenesis and even the smallest polyps have malignant potential. In addition, polyps in patients with Lynch syndrome are more often non-polypoid and proximally located, and therefore more difficult to recognize. Increasing polyp and adenoma detection rates with CADe systems is therefore of importance. Recently Fujifilm has developed a new technology known as *CAD EYE* to support colonic polyp detection and characterization during colonoscopy, utilizing Fujifilm's medical AI technology named REiLI (CADE-EYE, Fujifilm, Japan). Recently, in an image-based study setting, this CAD EYE detection system showed a sensitivity, specificity and accuracy of 92.9%, 90.6% and 91.7%, respectively [24]. To this date, no study has assessed this CAD EYE Detection technique in a comparable fashion for adenoma detection in patients with Lynch syndrome or regular surveillance patients.

Study objective

To compare adenoma detection rates of colonoscopy with and without a CADe system during surveillance colonoscopy of patients with Lynch syndrome.

Study design

International, multicenter, parallel, randomized controlled trial

Intervention

HD-WL endoscopy with computer aided detection system

Study burden and risks

Each colonoscopy is associated with a small, but not negligible risk of bleeding (~1%) or perforation (~0.1%). The use of the CADe does not increase the risk of endoscopy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Diagnosis of Lynch-syndrome, with a germline mutation in one of the MMR genes (MLH1, MSH2, MSH6) or deletions in the 3* region of the EpCAM gene
- Age >18 years
- Surveillance colonoscopy for Lynch syndrome.

Exclusion criteria

- Recent surveillance colonoscopy within 1 year from current exam (e.g. after piecemeal EMR) or patients referred for endoscopic evaluation of known colorectal neoplasia.
- Colonoscopy planned for the evaluation of symptoms like rectal blood loss, recent change in bowel habits, weight loss or anemia.
- Patients with a concurrent diagnosis of (serrated) polyposis syndrome or inflammatory bowel disease.
- Patients who are unwilling or unable to give informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	160
Type:	Anticipated

Medical products/devices used

Generic name:	CADE-EYE;Fujifilm;Japan
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL77827.018.21