MAGENTIQ-COLO CSC study Evaluation of the diagnostic performance of computer-aided polyp size classification of the MAGENTIQ-COLO during real-time colonoscopy

Published: 27-02-2025
Last updated: 25-03-2025

The primary objective of the study is to assess the diagnostic performance of the endoscopist performing a MAGENTIQ-COLO CADx-assisted colonoscopy to classify polyps as diminutive (5mm) compared to size classification using open biopsy forceps, or...

Ethical review	Approved WMO
Status	Pending
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON57323

Source
ToetsingOnline

Brief title
MAGENTIQ-COLO CSC study

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Colorectal polyps, polyps

Research involving
Human

Sponsors and support

Primary sponsor: Magentiq Eye LTD.
Source(s) of monetary or material Support: Industrie; Magentiq Eye LTD.

Intervention

Keyword: Artificial Intelligence, Colonoscopy, Computer-aided characterization

Outcome measures

Primary outcome

The diagnostic performance of the CADx-assisted optical diagnosis to correctly classify colorectal polyps as diminutive (<=5mm) or non-diminutive (>5mm). This will be measured by the sensitivity and specificity of the CADx-assisted optical diagnosis compared to the size classification of the polyp using open biopsy forceps, or polypectomy snare, of known diameter.

Secondary outcome

- The diagnostic performance of high-confidence CADx-assisted optical diagnosis to correctly identify diminutive colorectal polyps as neoplastic (adenoma or SSL). This will be measured by the sensitivity and specificity of the CADx-assisted optical diagnosis compared to the reference standard pathology diagnosis.

- The ability of the CADx-assisted optical diagnosis to correctly assign post-polypectomy surveillance intervals. This will be measured by the agreement rate of high-confidence CADx-assisted optical diagnosis for polyps <=5mm (cutoff based on the reference gold standard of this study) combined with the pathological diagnosis for polyps >5mm

- The diagnostic performance of CADx-assisted optical diagnosis to correctly

identify diminutive polyps in the rectosigmoid as neoplastic. This will be measured by the negative predictive value (NPV) of the high-confidence CADx-assisted optical diagnosis ompared to the reference standard pathology diagnosis.

-The rate of high-confidence neoplastic diagnoses (size and optical diagnosis) of diminutive colorectal polyps between standard visual inspection, the CADx system diagnosis, and CADx-assisted optical diagnosis.

Study description

Background summary

Colonoscopy is the gold standard for the detection and removal ofdetecting and removing premalignant colorectal polyps. Recommended post-polypectomy surveillance intervals are primarily based on pathological diagnosis and polyp size. However, accurate estimation of polyp size remains challenging, potentially influencing post-polypectomy surveillance intervals. Inaccuracies in size estimation may lead to either unnecessary or prematurely scheduled surveillance colonoscopies when overestimating size or lead to an increased risk of post-colonoscopy colorectal cancer or advanced neoplasia when underestimating size. Furthermore, diminutive (1-5mm) polyps pose challenges due to their high incidence and frequent pathological assessment. Proposed strategies to reduce this burden, such as the European Society of Gastrointestinal Endoscopy (ESGE) *resect-and-discard' strategy, are infrequently used as non-expert endoscopists often do not meet diagnostic thresholds when using standard visual inspection. The MAGENTIQ-COLO computer-aided diagnosis (CADx) system by Magentiq Eye LTD, Haifa, Israel, addresses these challenges by providing real-time size estimation and polyp characterization.

Study objective

The primary objective of the study is to assess the diagnostic performance of the endoscopist performing a MAGENTIQ-COLO CADx-assisted colonoscopy to classify polyps as diminutive (<=5mm) or non-diminutive (>5mm) compared to size classification using open biopsy forceps, or polypectomy snare, of known diameter. This will be measured by comparing the sensitivity and specificity between the two size classifications.

Secondary objectives include:
-To assess the diagnostic performance of the endoscopist performing a MAGENTIQ-COLO CADx-assisted colonoscopy to diagnose diminutive (rectosigmoid) colorectal polyps as neoplastic (adenoma or SSL) with high-confidence compared to the pathology diagnosis. This will be measured by the sensitivity and specificity between the two diagnoses;

- To assess whether performing a MAGENTIQ-COLO CADx-assisted colonoscopy meets the PIVI-1 and PIVI-2 criteria for real-time endoscopic assessment of the histology of diminutive colorectal polyps as proposed by the American Society for Gastrointestinal Endoscopy (ASGE).
o PIVI-1 criterium: >=90% agreement in assigning ASGE post-polypectomy surveillance intervals. This assessment is based on the high-confidence CADx-assisted optical diagnosis by the endoscopist for polyps <=5mm (cutoff based on the reference polyp size standard) in combination with pathological assessment for polyps >5mm. The comparator is the post-polypectomy surveillance intervals based on the pathological diagnosis of all identified polyps.
o PIVI-2 criterium: >=90% negative predictive value of the high-confidence CADx-assisted optical diagnosis of diminutive rectosigmoid polyps as neoplastic (adenoma or SSL) compared to pathological diagnosis.

- To assess the rate of high-confidence optical diagnoses (size and pathology) of using MAGENTIQ-COLO compared to the rate of high-confidence optical diagnoses using standard visual inspection.
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Study design

This is an international, multicenter, prospective study to evaluate diagnostic performance compared to a reference standard

Intervention

CADx-geassisteerde colonoscopie

Study burden and risks

The risk of (serious) adverse events associated with MAGENTIQ-COLO-assisted colonoscopy is comparable to that of conventional colonoscopy, as determined in our prior randomized, controlled trial. Although the described study procedures may lead to slightly prolonged colonoscopy procedural times compared to conventional methods, it is anticipated that patients will derive benefits from MAGENTIQ-COLO-assisted colonoscopy. Our aforementioned previous trial demonstrated a notable 37% increase in adenoma detection with the use of the MAGENTIQ-COLO (Maas, M. et al. (2024) Lancet Digital Health).

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

Individuals aged >=45 - <=80 years old, who are scheduled for non-iFOBT screening or surveillance colonoscopy.

Exclusion criteria

. In situ polyps with known histology.
2. No colorectal polyps detected during colonoscopy.
3. Known or suspected Inflammatory bowel disease.
4. Polyposis syndrome (e.g., familial adenomatous polyposis, serrated polyposis).
5. Non-hereditary polyposis syndromes (e.g. Lynch syndrome).

6. History of chemotherapy or radiation therapy for colorectal lesions.
7. Pregnancy.
8. Has a referral for therapeutic procedure (i.e., endoscopic mucosal resection, intervention to stop a lower gastro-intestinal bleeding, etc.).
9. Inability to undergo polypectomy (e.g., incorrect continued use of anticoagulants, comorbidities) or patient refusal, as assessed by the endoscopist.
10. Inability to provide informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	MAGENTIQ-COLO
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-02-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT06568523
CCMO	NL86897.078.24