Randomized Two Arm Multi-Center Study to Evaluate the Safety and Efficacy of the Use of Magentiq Eye's Automatic Polyp Detection System (ME-APDS) During Colonoscopy

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• Evaluate the safety of ME-APDS in subjects during colonoscopy.• Assess the efficacy of ME-APDS - whether the use of the ME-APDS improves the Adenoma Per Colonoscopy APC when compared to conventional colonoscopy (CC). Thereby we aim to further…

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

Summary

ID

NL-OMON50965

Source
ToetsingOnline

Brief title
Magentiq Eye Study

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign

Synonym
Colorectal adenomas and polyps

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Adenoma, Colonoscopy, Computer Aided Detection (CADe), Polyp

Outcome measures

Primary outcome

Safety Endpoints

• Incidence of Serious AEs (SAEs)

Efficacy Endpoints

Co-Primary

• Adenoma Per Colonoscopy (APC): between the Magentiq Eye-assisted colonoscopy and conventional colonoscopy, calculated only on the first examination.

• Adenoma Per Extraction (APE): between the Magentiq Eye-assisted colonoscopy and conventional colonoscopy, calculated only on the first examination.

Secondary outcome

• The Adenoma Miss Rate (AMR), calculated as the number of ade-nomas detected in the second examination divided by the total number of adenomas detected in the both examinations, between Magentiq Eye-assisted colonoscopy as first examination (AMR of MAEC) and conventional colonoscopy as first examination (AMR of CC).

• Adenoma Detection Rate (ADR), calculated as the number of pa-tients who have one or more adenomas detected and removed di-vided by the total number of

patients, between the Magentiq Eye-assisted colonoscopy and conventional

colonoscopy, calculated only on the first examination.

Study description

Background summary

Recently, we have developed the Magentiq Eye*s Automatic Polyp Detection System (ME-ADPS). Pre-clinical studies show an 89% sensitivity and a 98.4% specificity, and the last offline test with the system showed that 97.3% of the polyps were detected (where at least one frame of the polyp shall be detected in order to define the polyp as detected) with system precision of 96%.

Study objective

• Evaluate the safety of ME-APDS in subjects during colonoscopy.
• Assess the efficacy of ME-APDS - whether the use of the ME-APDS improves the Adenoma Per Colonoscopy APC when compared to conventional colonoscopy (CC). Thereby we aim to further improve the care that is provided to patients at risk of developing CRC.
• Compare the Adenoma Per Extraction (APE) of the ME-APDS group with the CC group.
Secondary objectives of this study are
• Compare the Adenoma Miss Rate (AMR) of the ME-APDS group with the CC group.
• Compare the Adenoma Detection Rate (ADR) of the ME-APDS group with the CC group.

Study design

Randomized, two arm colonoscopy trial, including 952 patients. Participants will be randomized twice

1. Randomization to undergo ME-APDS assisted colonoscopy or conventional colonoscopy
2. Randomization to undergo a second colonoscopy examination

The aim of the second randomization is to have a small group of patients (136) that undergo both colonoscopy procedures, to compare the adenoma miss rate (AMR).

Intervention

Colonoscopy

Study burden and risks

Patients will be enrolled for a period starting up to 30 days prior to procedure date and ending after 30 days of follow up from procedure date. The risks of adverse events for Magentiq Eye assisted colonoscopy are believed to be equivalent to conventional colonoscopy, except of that the rise in APC might also lead to longer procedure times and more adverse events such as delayed bleeding, caused by an increased number of polypectomies. Apart from the randomization patients will be treated as per protocol. Probably more polyps will be detected during Magentiq Eye assisted colonoscopy, depending on the type of polyp this might have a beneficial effect on the morbidity and mortality resulting from colorectal carcinoma.

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

1. Able to provide written informed consent prior to any study procedures;
2. Able to communicate clearly with the Investigators and study staff;
3. Males and females aged between 18 - 90 years of age;
4. Referred and Scheduled for either screening or surveillance colonoscopy which is sched-uled every 3 to 10 years;
5. Has not been referred to the test after positive iFOBT.

Exclusion criteria

1. Has a known or suspected colorectal tumor or polyp on referral;
2. Has a referral for therapeutic procedure (i.e. endoscopic mucosal resection, intervention to stop a lower gastro-intestinal bleeding, etc.);
3. Has not corrected anticoagulation disorders;
4. Inability to provide informed consent;
5. Has any clinically significant condition that would, in the opinion of the investigator, pre-clude study participation;
6. Unable or unwilling, in the opinion of the Investigator to comply with the requirements of the protocol;
7. Employees of the investigator and study site or the sponsor, as well as family members of the employees or the investigator or the sponsor;
8. Has inadequate bowel preparation, defined as: Boston Bowel Preparation Score (BBPS) <6 or any segment <2 (each procedure report will include the BBPS);
9. Any woman who is pregnant or potentially pregnant.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	30-11-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Magentiq Eye Automatic Polyp Detection System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-07-2021
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	NL77061.091.21

Study results

Results posted:	24-09-2024
Actual enrolment:	7

First publication
06-03-2024