Feasibility and accuracy of the Olympus Extra Wide Angle View colonoscope for the detection of colorectal lesions in comparison with the Exera III study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22448

Source
NTR

Brief title
EWAVE

Health condition

Adenoma Miss Rate during colonoscopy

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Olympus Medical Systems

Intervention

Outcome measures

Primary outcome

Adenoma detection rate of the Olympus Extra Wide Angle View colonoscope

Secondary outcome

- Sensitivity of the Olympus Extra Wide Angle View colonoscope for the detection of advanced colorectal adenomas in comparison to data from the Exera III study, overall and in subgroups (adenoma size, form, location).

- Evaluation of caecal insertion time using the Olympus Extra Wide Angle View colonoscope with responsive insertion technology in comparison to caecal insertion times gained during the Exera III study.

- Evaluation of ileocaecal valve insertion success using the Olympus Extra Wide Angle View colonoscope in comparison to ileocaecal valve insertion success gained during the Exera III study.

- Evaluation of retroflex view using the Olympus Extra Wide Angle View colonoscope in comparison to the retroflex view gained during the Exera III study.

- Adverse events of the Olympus Extra Wide Angle View colonoscope in comparison to the Exera III study.

Study description

Background summary

Colonoscopy is the gold standard for finding colorectal cancers and precursor lesions, adenomas. Unfortunately recent studies show there is still a high adenoma miss-rate with the current endoscopic techniques. Some adenomas hide behind valve and are therefore missed. Olympus developed a new device that provides the endoscopist an enlarged view. The expectation is that due to this enlarged view more adenomas are detected compared to conventional colonoscopy. The results will be compared with the results of the EXERA III study

Study objective

Increased adenoma detection rate due to the enlarged colonoscopic view

Study design

01-03-2015 data analysis

Intervention

Colonoscopy with extra wide angle view colonoscope

Contacts

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Eligibility criteria

Inclusion criteria

- Age greater than or equal to 18 years

- High risk for colorectal cancer: FOBT positive, personal or familial (first degree relatives) history of colorectal cancer or colorectal adenoma, patients with symptoms suggestive of colorectal neoplasm: rectal bleeding, recent change in frequency and consistency of stools.

- Status 1 and 2 of the ASA classification (see Appendix I)

- Signed informed consent

Exclusion criteria

- Mental or physical condition that can adversely affect the preparation or conduct of the examination or which precludes compliance with the study and / or device instructions.

- Inability to undergo bowel cleansing for colonoscopy.

- Prior abdominal surgery of the gastrointestinal tract (other than uncomplicated appendectomy or cholecystectomy).

- Known or suspicion of inflammatory bowel disease.

- Known large (> 2 cm) colorectal polyp for polypectomy

- Colonic diverticulosis complication within 3 months prior inclusion.

- Very high risk for colorectal cancer, history of extensive polyposis, patients with known genetic disease (Familial Adenomatous Polyposis (FAP), Hereditary Non-Polyposis Colorectal Cancer (HNPCC)).

- Coagulation abnormalities or taking drugs affecting coagulation.

- Life threatening conditions

- Status > 2 of the ASA classification (see Appendix I).

- Renal insufficiency or any contraindication or medication contraindicating the administration of bowel cleansing.

- Female patients who are pregnant or nursing, or of childbearing potential and are not using adequate contraception.

- Participation in another clinical trial within 30 days prior to the Screening Visit or during this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-08-2014
Enrollment:	429
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41267
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4316
NTR-old	NTR4536
CCMO	NL46414.018.13
OMON	NL-OMON41267

Study results