Evaluation of a Second Generation High Definition and Narrow Band Imaging System for the Detection and Characterization of Colorectal Adenomas (EXERA III Colorectal Adenoma Study)

Published: 22-01-2013
Last updated: 26-04-2024

Evaluation of the effectiveness of a new system HD2/NBI2 to improve the detection of colorectal neoplastic lesions during colonoscopy in comparison to the former generation with currently highest share of the installed base (nonHD-nonNBI system i.e...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON39244

Source
ToetsingOnline

Brief title
EXERA III Colorectal Adenoma Study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal adenoma

Research involving
Human

Sponsors and support

Primary sponsor: Olympus
Source(s) of monetary or material Support: OLYMPUS EUROPA HOLDING GMBH

Intervention

Keyword: Colorectal Adenomas, Detection and Characterization, Evaluation, Imaging System

Outcome measures

Primary outcome

The primary endpoint:

Sensitivity of HD2/NBI2 colonoscopy for the detection of colorectal adenomas in

comparison to nonHD-nonNBI colonoscopy.

Secondary outcome

The secondary endpoints:

• Sensitivity of HD2/NBI2 colonoscopy for the detection of advanced

colorectal adenomas in comparison to nonHD-nonNBI colonoscopy.

• Sensitivity of HD2/NBI2 colonoscopy for the detection of colorectal

adenomas larger than 10mm in diameter in comparison to nonHD - nonNBI

colonoscopy.

• Gross appearance (Paris Classification) of adenomas identified in the group

HD2/NBI2 compared to the nonHD-nonNBI group.

• Location of adenomas identified in the group HD2/NBI2 compared to the

white light group.

• Sensitivity of NBI colonoscopy for the detection of hyperplastic polyps in

comparison to nonHD-nonNBI colonoscopy.

• Adenoma miss rate using HD2/NBI2 in comparison to nonHD-nonNBI imaging.

• Prevalence of patients with at least one adenoma using HD2/NBI2 in

comparison to nonHD-nonNBI colonoscopy.

• Evaluation of the sensitivity of NICE criteria using HD2/NBI2 *near focus* to

predict the nature of adenomatous

colorectal polyps < 10mm in diameter.

• Evaluation of caecal insertion time using HD2/NBI2 colonoscope with

responsive insertion technology in comparison to caecal insertion time using

nonHD-nonNBI colonoscope.

• Adverse events of HD2/NBI2 colonoscopy in comparison to nonHD- nonNBI

colonoscopy

Study description

Background summary

A second generation HDTV and NBI will be soon available. This second generation NBI will have a brighter image than the first generation due to various improvements in the design of the light source, video processor and CCD. As the failure of first generation NBI to enhance adenoma detection could be partly explained by the darkness of the images provided by NBI function, this second generation NBI still has a potential role for detection of colonic adenomas and this role has to be evaluated in a randomized cross-over study. The question is to know if the combination of second generation HDTV / 170° FOV (HD2) plus NBI second generation (NBI2) could help to better detect colorectal adenomas in comparison to non HDTV / 140° FOV without NBI function. In order to limit the number of patients to be included, high risk patients for colorectal cancer will be selected. In such group mixing FOBT positive patients and patients with a familial or personal history of colorectal neoplastic lesions, the prevalence of patients with at least one adenoma is expected to be 35%. The new generation HD2/NBI2 colonoscope will further more incorporate new responsive insertion technology. This consists of a passive bending section at the distal part and various other improvements in the insertion tube design. The passive bending aims to help the operators to more easily negotiate acute angulations of the colon when inserting the endoscope and to reduce the time for insertion of the endoscope to the caecum. Further elements of responsive

insertion technology include a high force transmission design of the entire insertion tube aiming at maximizing the push force transmission to the tip as well as variable stiffness that allows stiffening of the insertion part during examination to prevent recurrence of looping. Evaluation of this new responsive insertion technology to reduce time for inserting the endoscope will be a secondary parameter to be analyzed during this study.
This new generation HD2/NBI2 could also help to better characterize the polyps. First generation HDTV / 170° FOV imaging has also not demonstrated any effect to enhance adenoma and according to industry sources non HDTV / 140° FOV imaging is still mainly used for colonoscopy in Europe. The second generation HDTV endoscope technology consists of a dual focus optical lens / aperture in combination with a further improved CCD design. With its new dual focus lens system in *near focus* mode this optical system can deliver higher to first generation HDTV *close focus* image magnification at levels identical to the magnification level of commercially available dedicated zoom endoscopes in *tele mode*. Also in the *far focus* mode the new dual focus scope delivers imaging resolution clearly surpassing the level once established by first generation HDTV endoscopes.
Characterization of a colorectal polyp during colonoscopy has 2 major potential advantages: 1 - to determine if the polyp is neoplastic (adenoma) or not (hyperplastic) and then to decide whether or not it is necessary to remove the polyp or to analyze it once removed. To avoid unnecessary resection or unnecessary analysis of polyps that are not at risk may have major implications for reducing morbidity and procedure cost, 2 - to determine if in a neoplastic polyp there is a deeply invasive submucosal cancer leading to avoid endoscopic resection and favor a surgical resection. Up to now in Europe and the USA, polyp characterization is very little done unlike in Japan: the rule is to systematically remove all polyps except those who are obviously non-neoplastic and less than 10mm in diameter in the rectum. Japanese operators instead characterize polyps by zoom chromoscopy (with dye spraying). Why this difference in practice between Japan and Western countries? 1 - Chromoscopy is little used in the West because it is time consuming, has a certain cost (catheter) and is well not remunerated 2 - the Western versions (color CCD, 100 series) of endoscope zoom are less easy to use than the Japanese versions (Black and white CCD, 200 series).
As NBI is very easy to activate and as zoom magnification is not even mandatory for NBI characterization (60) NBI function could therefore allow the West to limit removal and histological analysis of non - risk polyps. Such policy (called DISCARD) has already been tested with success in UK, where endoscopes used are similar to the Japanese endoscopes (black and white CCD, 200 series) (63). For polyps less than 10 mm in size, in-vivo optical diagnosis is considered as an acceptable strategy to assess polyp histopathology and future surveillance intervals. A classification of polyps using the NBI (NICE classification) has been established between experts from Europe, Japan and USA. This classification separates adenomatous polyps (type B) from hyperplastic polyps (type A), and also distinguishes adenoma with massive submucosal cancer (type C). The purpose of this study is to evaluate the

accuracy of this classification using second generation NBI and to evaluate its role to avoid unnecessary resections or to avoid unnecessary histological analysis. At the same time, the new dual focusing system which aims to provide easy to obtain high magnification views for better and easier analysis will be evaluated.

Study objective

Evaluation of the effectiveness of a new system HD2/NBI2 to improve the detection of colorectal neoplastic lesions during colonoscopy in comparison to the former generation with currently highest share of the installed base (nonHD-nonNBI system i.e. 160/165 series)

Study design

Multicenter cross-over randomized controlled study

Intervention

Back-to-back colonoscopy with two different colonoscopy systems.

Study burden and risks

Risks of the colonoscopy procedure:
The risks of colonoscopy are well established. The procedures within this study are consistent with usual routine colonoscopy. No new study-related colonoscopic risks are anticipated within the study. As the patient will be evaluated with two colonoscopy systems within the same sitting, it is conceivable that slightly increased risks may be associated with lengthened anesthesia or sedation time.
It is to be noted that within the European scope of this clinical study the routine administration of anesthesia or sedative medications for colonoscopic procedures varies widely between the investigational sites. These issues will be appropriately addressed within the informed consent process.
Benefits from participating in the study:
Each study participant will be examined using two acknowledged colonoscopy systems by two experienced gastroenterologists. It is expected that through this process, an optimal identification of potentially cancerous polyps may be obtained. At the same time, a guarantee that all potentially cancerous polyps will be found cannot be made.

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

• 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.
• 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 phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2013
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	EXERA-III-Colonoscope (HQ-190-series)

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-01-2013
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
Other	EUDAMED CIV-11-06-000845
CCMO	NL37543.018.12

Study results

Date completed:	09-12-2014
Actual enrolment:	91