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Study on narrow band imaging versus conventional colonoscopy for polyps detection in patients with positive fecal occult blood test undergoing colonoscopy screening

Submission date
22/01/2013

Recruitment status
No longer recruiting

Registration date
12/03/2013

Overall study status
Completed

Last Edited
04/10/2016

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The detection and removal of adenomatous polyps (small non-cancerous growths that develop in the large bowel) may prevent colorectal cancer and save lives. Colonoscopy is the standard procedure for the detection and removal of polyps. However, colonoscopy still misses between 5% and 24% of polyps, which can result in the development of colorectal cancer. It is also unable to distinguish different types of polyp, leading to the removal of all polyps found, thus increasing the costs and risks. In order to overcome these limitations, there have been many attempts to improve the diagnostic accuracy of colonoscopy. The aim of this study is to find out whether the use of a new endoscopy technology called narrow band imaging (NBI) increases the detection rate of advanced adenomas compared with High Definition White Light colonoscopy (HD-WL).

Who can participate?
Patients aged 55-64 undergoing colonoscopy

What does the study involve?
Participants are randomly allocated to undergo colonoscopy with either HD-WL or NBI. The colonoscope is inserted into the rectum and advanced to the cecum (the beginning of the large intestine). The endoscopist carefully explores the whole colon, and the procedure is timed by the endoscopist using a stopwatch. Polyps detected are documented for their size, location and shape, and removed and sent in separate jars for diagnosis by a histopathologist. The number of adenomas and advanced adenomas are counted in both groups.

What are the possible benefits and risks of participating?
The possible benefits include increased detection of advanced adenomas. The technique of colonoscope insertion and withdrawal does not change, so no additional risk for the patient is expected.

Where is the study run from?
The study is run from two tertiary referral centers for digestive endoscopy (Torino and Novara) of North-Western Italy

When is the study starting and how long is it expected to run for?
May 2008 to June 2011

Who is funding the study?
University of Turin, Molinette Hospital, Torino (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Narrow band imaging versus high definition white light colonoscopy for the detection of colorectal polyps in patients with positive fecal occult blood test undergoing colonoscopy screening: results of a prospective randomized controlled trial

Study objectives
The use of Narrow Band Imaging (NBI) increases the detection rate of advanced adenomas compared with High Definition White Light colonoscopy (HD-WL)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Intercompany A.O.U.(Comitato etico Interaziendale A.O.U.) San Giovanni Battista di Torino, Corso Bramante 88 10126 Torino (Italy), 21/04/2008, ref - Protocol: CEI/231

Study design
Interventional multicentre randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with positive FOBT harbour a risk of colorectal cancer of about 5% and of advanced adenomas of about 40%

Interventions
A total of six experienced endoscopists each having performed > 5000 standard colonoscopies and > 50 NBI colonoscopies participate in the study. For all the study procedures, high-resolution wide-angle (170 degrees) video colonoscopes with push button switch from WL to NBI (Olympus HD 180 series, Olympus Corp., Hamburg, Germany) will be used.

Patients will be randomized to undergo colonoscopy with either HD-WL or NBI by a computer-generated randomization sequence.

Procedures will be performed with conscious sedation if not refused by the patient. The colonoscope will be inserted into the rectum and advanced to the cecum by using HD-WL modality in each patient and no attempt will be made to detect polyps during insertion. The success of cecal intubation will be assessed by the endoscopist by the identification of the ileocecal valve and the appendix orifice. In patients randomized to the NBI arm, the NBI mode will be switched on at the start of the withdrawal phase. During the withdrawal phase, the endoscopist will carefully explore the whole colon from the cecum to the rectum with the assigned light; the entire procedure time and the withdrawal phase will be timed by the

endoscopist by using a stopwatch, which will be blocked whenever a polyp will be found and removed. Bowel preparation will be evaluated and graded as: optimal (minimal amount of liquid stools), sub-optimal (mainly liquid stools, no limitation of the examination), fair (liquid and semisolid stools), inadequate (impossibility to perform a reliable examination, repetition of procedure required).

Polyps detected during each procedure will be documented for their size, location and morphology (pedunculated, sessile, and non-polypoid). Non-polypoid (flat and depressed) lesions are defined as the lesions endoscopically high less than half wide, according to Paris classification.

Polyps will be removed and sent in separate jars for histopathological diagnosis by histopathologist who will be blinded to the coloscopy findings.

The definition of advanced adenoma includes all adenomas with a diameter ≥ 1 cm and/or villous component of at least 25%, and/or high-grade dysplasia.
Diminutive adenomas are defined as those with a diameter ≤ 5 mm.
Cancer is defined as the invasion of malignant cells beyond the muscolaris mucosa. Patients with intramucosal carcinoma or carcinoma in situ will be classified as having high-grade dysplasia.

Intervention Type
Procedure/Surgery

Primary outcome measure
To evaluate whether the use of NBI might increase the detection rate of advanced adenomas compared with High Definition White Light colonoscopy (HD-WL); so, the primary outcome measures will be the overall number of advanced adenomas detected in both groups and the number of advanced adenomas per patient. The definition of advanced adenoma includes all adenomas with a diameter ≥ 1 cm and/or villous component of at least 25%, and/or high-grade dysplasia.

Secondary outcome measures
To compare the ADR, defined as the percentage of patients with ≥1 adenomas, and the total number of adenomas. So, the secondary outcome measures will be the overall number of patients with at least one adenoma in both groups and total number of adenomas found in the patients according to their group.

Overall study start date
01/05/2008

Completion date
01/06/2011

Eligibility

Key inclusion criteria
All consecutive patients aged 55-64 years, either sex, referred to the Endoscopic Units of Torino and Novara for screening colonoscopy due to positive fecal occult blood test (FOBT)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Use of antiplatelet agents or anticoagulants that preclude removal of polyps
2. Refusal to participate or inability to give informed consent

Date of first enrolment
01/05/2008

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
Italy

Study participating centre
San Luigi Hospital
Orbassano
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Sponsor information

Organisation
University of Turin (Italy)

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Sponsor type
University/education

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ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University of Turin, Molinette Hospital, Torino (Italy) - Department of Gastroenterology and Hepatology

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration