

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

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| <b>Submission date</b><br>22/01/2013   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>12/03/2013 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>04/10/2016       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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?

Prof. Giorgio Saracco

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## Contact information

### Type(s)

Scientific

### Contact name

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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 colonoscopy findings.

The definition of advanced adenoma includes all adenomas with a diameter  $\geq 1$  cm and/or villous component of at least 25%, and/or high-grade dysplasia.

Diminutive adenomas are defined as those with a diameter  $\leq 5$  mm.

Cancer is defined as the invasion of malignant cells beyond the muscularis 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  $\geq 1$  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  $\geq 1$  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

Italy

10100

**Sponsor information****Organisation**

University of Turin (Italy)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.unito.it>

**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