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Assessing the additional neoplasia yield of EndoRings™ in a colorectal cancer (CRC) screening setting

Submission date
07/07/2016

Recruitment status
No longer recruiting

Registration date
12/07/2016

Overall study status
Completed

Last Edited
13/07/2016

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel (or colorectal) cancer is one of the most common types of cancer. If a person is suspected to have colorectal cancer, they may undergo a colonoscopy, an examination of the bowel using a device called a colonoscope. A colonoscope is a flexible tube that is attached to a camera and a light. It is inserted into the bowel though the rectum. The tube is pushed through the entire length of the bowel and is then slowly taken out again (withdrawn). The bowel is examined for signs of cancer (the presence of adenomas and polyps) during withdrawal. The EndoRings is a flexible silicone rubber device that can be attached to the end of a colonoscope. It has circular wings that stretch the walls of the colon and flatten them. This, in turn, increases how much of the colon that can be seen during a colonoscopy. Previous studies have shown that EndoRings colonoscopy is more likely to detect adenomas and polyps and are less likely to miss them (miss rate) than standard colonoscopy. This study is comparing the diagnostic yield (that is, how many patients are diagnosed with bowel cancer) and the number of adenomas and polyps are missed (the miss rate) of EndoRings colonoscopy with standard colonoscopy.

Who can participate?
Adults that have tested positive in respect to a immunochemical fecal test as part of a screening program to detect bowel cancer.

What does the study involve?
Participants are randomly assigned to one of four groups. Those in group 1 are given a standard colonoscopy. Those in group 2 are given a EndoRings colonoscopy. Those in group 3 are given a standard colonoscopy followed by a EndoRings colonoscopy (one immediately after the other). Those in group 4 are given a EndoRings colonoscopy followed immediately by a standard colonoscopy. If any adenomas or polyps are identified during the procedures they are removed and analysed if appropriate. All patients are then called 30 days after the examination and asked about their experience.

What are the possible benefits and risks of participating?
The possible benefit to participating in this study is the identification of precancerous lesions (for example, polyps), leading to a reduced risk of developing CRC. No risks are expected.

Where is the study run from?
Regina Margherita Hospital, Rome (Italy)

When is the study starting and how long is it expected to run for?
April 2016 to January 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Cesare Hassan
cesareh@hotmail.com

Contact information

Type(s)
Public

Contact name
Dr Cesare Hassan

Contact details
ASL RM1
via Emilio Morosini 30
Rome
Italy
00153
+390658446608
cesareh@hotmail.com

Additional identifiers

Protocol serial number
001

Study information

Scientific Title
To assess the additional yield of colorectal neoplasia at colonoscopy with EndoRings™ in a colorectal cancer (CRC) screening setting: a multicentre randomized trial

Study objectives
Objective:
To compare the additional diagnostic yield and the miss rate obtained by using EndoRings colonoscopy (index test) to the yield obtained by standard colonoscopy (reference test). Given the suggested association of a higher miss rate of serrated and flat lesions with an increased risk

of early post-colonoscopy CRC, the added value of the new technique in reducing the miss rate of these lesions will be assessed.

Primary aims:
1. Assessing the additional yield and miss rate of advanced adenomas, adenomas, and the proportion of patients detected with 3 or more adenomas (serrated adenomas will be also be considered in the calculation) in patients when using EndoRings colonoscopy as compared to standard colonoscopy in both a simple (detection rate) and tandem (miss rate) assessment
2. Comparing the change in adenoma detection rate (ADR) in the detection-arms with the miss-rate in the tandem arms

Secondary aims:
1. Comparing overall adenoma and polyp detection rate, flat adenoma and serrated polyps /adenomas detection rate of the two methods
2. Comparison of the size of multiple lesions detected by the two methods
3. Comparison of the detection rate of neoplasia by colonic site: distal (rectum, sigmoid and descending colon) and proximal (proximal to the descending colon)
4. Differences in the surveillance guidelines post-colonoscopy when comparing the two arms
5. Comparison of the time required to reach the cecum
6. Comparison of the withdrawal and total procedure time
7. Assessing the learning curve of participating endoscopists
8. Assessing patient's experience
9. Assessing the specific contribution of the EndoRings stretching effect in the detection of lesions located in flexures and between folds
10. Assessing the specific contribution of the EndoRings stabilization effect during endo-therapy interventions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Lazio 1 (Comitato Etico Lazio 1), 16/06/2016, ref: N°1256

Study design
Multicentre interventional randomized study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Colorectal adenomas and serrated polyps

Interventions
The EndoRings is a flexible silicone rubber add-on device designed to be attached to the distal tip of the designated endoscope. The product features a short tube like shape with two flexible circular layers of wings. It's function is to flatten folds in the colon and stretch its walls during withdrawal to improve visibility and therefore adenoma detection rate (ADR).

Patients will be randomized to undergo one of the following:

1. Colonoscopy with WL (white light)
2. Colonoscopy with WL+EndoRings
3. Tandem colonoscopy WL+EndoRing (first)-WL (second)
4. Tandem colonoscopy WL (first)-WL+EndoRing (second)

Randomization will be stratified by gender, age group (50-59, 60-75 years of age) and screening history (first versus subsequent test). Eight series of sealed envelopes containing the indication of the randomization arm were provided to each centre: the endoscopist performing the examination, after having obtained patient's consent will open the next unused envelope in the relevant series to know the examination approach to be adopted with the patient. Each endoscopist must do a minimum of 25 patients in each arm (total of 100 patients).

Examination procedure:
Experienced endoscopists each having performed > 5000 standard colonoscopies and > 5 EndoRings colonoscopies in standard colonoscopy indication patients within the previous 6 months participate in the study. In order to reduce operator related variability, only 2 endoscopists in each center will be involved in the study. For study procedures, standard or high definition scopes will be used for standard scope (ie, as in clinical routine), while same scope's models+EndoRings will be used in the EndoRings arm. No chromoendoscopy or light-modification technologies will be used. Photo documentation as well as notation of location and estimated size of all lesions the endoscopist is not able to remove (except those thought to be hyperplastic polyps in the rectum). Electronic copies of the images of those polyps left in place will be saved. All patients will undergo routine bowel preparation according to a standardized protocol as is used in the study center. Four liter split prep bowel preparation will be used. All patients consume low-fiber or fiber free diet for at least one day in advance of the procedure.

In the tandem arms, the same endoscopists will perform both of the consecutive procedures. In the case one of the two is incomplete, the patient will be excluded from primary analysis.

All patients examined will be called 30 days after the exam by trained interviewers, who will ask for their consent to answer a brief questionnaire designed to assess post-examination adverse events and patient's experience of the exam.

Intervention Type
Device

Primary outcome(s)
Detection rate of (advanced) neoplasia with and without EndoRIng (95% CI)

Key secondary outcome(s))
1. Detection rate of adenoma/polyp/flat adenoma/serrated polyps/adenomas, determined though colonoscopy results from each of the study arms
2. Detection rate of neoplasia by colonic site: distal (rectum, sigmoid and descending colon) and proximal (proximal to the descending colon)
3. Time required to reach the cecum, as measured in minutes during the insertion of the scope from the anus to the caecum
4. Withdrawal time, as measured in minutes during the withdrawal of the scope from the caecum to the anus
5. Patient's experience, as measured with a visual analogue scale rated from 1 to 7

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Subjects positive at immunochemical fecal test at organized screening program in countries where organized programs are running
2. Sporadic screening in those countries where programs are not running

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Previous colonoscopy in 5 years

Date of first enrolment
01/08/2016

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Italy

Netherlands

Spain

Study participating centre
Regina Margherita Hospital (Nuovo Regina Margherita Hospital)
Rome
Italy
00153

Sponsor information

Organisation
ASL RM1

ROR
https://ror.org/00eq8n589

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request