

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

|                                        |                                                   |                                                                                                              |
|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>07/07/2016   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>12/07/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>13/07/2016       | <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

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 through 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 The tube is pushed through the entire length of the bowel and is then slowly taken out again (withdrawn).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