

# Comparing colonoscopy, sigmoidoscopy and fecal occult blood test for colorectal cancer screening

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<b>Registration date</b> 28/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/11/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## 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

## Acronym

SCORE 3 (Screening COloREctal)

## Study objectives

Comparisons of attendance, detection rates and acceptability of total colonoscopy, flexible sigmoidoscopy and fecal occult blood test (FOBT) as primary screening tests for colorectal cancer.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Piedmont region ethics board, date of approval: 17/06/2002 (ref: 8151/28.3)

## Study design

Interventional randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Screening

## Participant information sheet

## Health condition(s) or problem(s) studied

Colorectal cancer, colorectal polyps

## Interventions

Patients, after informed consent, were individually randomized from rosters of GPs or from residents in specific districts or city neighborhoods, either to total colonoscopy or flexible sigmoidoscopy or FOBT.

1. Colonoscopy: oral bowel preparation with sodium phosphate solution (two litres). Mild dietary restrictions (i.e. to increase the uptake of water and to reduce consumption of foods rich in fibers the day before the test) recommended. Colonoscopy performed by gastroenterologists in hospital endoscopy units. No standard protocol for sedation. If the baseline colonoscopy could not be completed to the cecum, the patients were referred for a Double Contrast Barium Enema (DCBE), whenever advanced adenomas (see Polyp classification) were detected in the segments

examined. DCBE was not routinely indicated in the case of a negative incomplete colonoscopy, due to patient's intolerance.

2. Sigmoidoscopy: bowel preparation was limited to a single enema (133 ml of 22% sodium phosphate) self-administered at home two hours before the test. No dietary restriction recommended. Screening undertaken by gastroenterologists in hospital endoscopy units. Aim of the examination: to advance the endoscope beyond the sigmoid-descending colon junction under adequate bowel preparation. Polyps smaller than 10 mm detected during the flexible sigmoidoscopy were removed immediately and sent for histological assessment. Subjects with polyps larger than or equal to 10 mm, as well as those detected with advanced adenomas (see polyp classification) referred for total colonoscopy. Subjects with suspected colorectal cancer or with polyps too large to be removed endoscopically referred for surgery.

3. FOBT: immunochemical test performed on a single sample without any dietary restriction. All cards stored at 4°C and shipped weekly to one central laboratory (Laboratorio di Citopatologia, CSPO - Florence). Patients with positive test called by the study staff and they are offered an appointment date for a total colonoscopy.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Attendance and detection rate to total colonoscopy, flexible sigmoidoscopy and FOBT as primary screening tests.

### **Secondary outcome measures**

Acceptability, complication rates, side effects and costs associated with screening procedures.

### **Overall study start date**

01/10/2002

### **Completion date**

31/01/2004

## **Eligibility**

### **Key inclusion criteria**

Men and women aged 55 to 64 who had not been recruited in previous SCORE trials (SCORE and SCORE 2).

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

**Target number of participants**

18,000 subjects

**Key exclusion criteria**

1. Patients unable to give informed consent
2. Patients with terminal illness, inflammatory bowel disease, personal history of polyps or colorectal cancer
3. Patients with two first degree relatives with colorectal cancer
4. Patients who had a colorectal endoscopy or FOBT within the previous two years

**Date of first enrolment**

01/10/2002

**Date of final enrolment**

31/01/2004

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

CPO Piemonte and ASO San Giovanni Battista

Turin

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## **Sponsor information**

**Organisation**

Italian League Against Cancer (LILT) (Italy)

**Sponsor details**

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**Sponsor type**

Government

**Website**

[www.lagatumori.it](http://www.lagatumori.it)

**ROR**

<https://ror.org/02g2x7380>

**Funder(s)****Funder type**

Government

**Funder Name**

Support for the study was provided by:

**Funder Name**

Grant from the Italian League against Cancer (LILT) (Italy) (Letter protocol number: 2001/3081/Sa/lr)

**Funder Name**

The following provided additional resources for the implementation of the study in Rimini, Biella, Milan, Verona and Turin, respectively:

**Funder Name**

a. Piedmont Regional Health Authority (Italy)

**Funder Name**

b. ULSS 20 Verona (Italy)

**Funder Name**

c. University of Milan (Italy)

**Funder Name**

d. Fondo "E Tempia" (Italy)

**Funder Name**

e. Istituto Oncologico Romagnolo (IOR) (Italy)

**Funder Name**

SOFAR s.p.a. (Italy) provided the enemas for the bowel preparation

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2007		Yes	No