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

Submission date 10/07/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2006	**Overall study status** Completed	
Last Edited 11/11/2009	**Condition category** Cancer	

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
Italy
10123

Sponsor information

Organisation
Italian League Against Cancer (LILT) (Italy)

Sponsor details
Via Torlonia, 15
Rome
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Sponsor type
Government

Website
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?
Results article	results	01/06/2007		Yes	No