

# Italian multicentre randomised controlled trial of 'once-only sigmoidoscopy'

<b>Submission date</b> 10/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/11/2021	<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**

Randomised controlled trial evaluating efficacy of 'one-only sigmoidoscopy' screening for colorectal cancer

**Acronym**

SCORE

**Study objectives**

The incidence of distal adenomas reaches a plateau at around age 60 years. Therefore, a single sigmoidoscopy followed by colonoscopy in people with high-risk distal adenomas may offer a long lasting protection.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local co-ordinating committees approved following approval from the Delibera Azienda USL 1 Torino on the 14th June 1995 (ref: 982/07/95)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Colorectal cancer screening

**Interventions**

Sigmoidoscopy offered once in the life in the intervention group; usual care in the control group.

**Sigmoidoscopy:**

Bowel preparation was limited to a single enema (133 ml of 22% sodium phosphate) self-administered at home 2 hours before the test. No dietary restriction recommended. Screening undertaken by gastroenterologists in hospital endoscopy units. Aim of the examination was to advance the endoscope beyond the sigmoid-descending colon junction under adequate bowel preparation. Polyps less than 6 mm detected during the FS were removed immediately and sent for histological examination. Subjects with polyps larger than 5 mm, or with advanced adenomas

(see polyp classification) referred for TC. Subjects with suspected CRC or with polyps too large to be removed endoscopically referred for surgery.

**Joint sponsor details:**

Italian National Research Council (CNR) (Italy)

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**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

To quantify the reduction in CRC incidence (measured at 10 years) and mortality (measured at 11 years).

**Secondary outcome measures**

1. To determine the duration of efficacy of a single flexible sigmoidoscopy, measured up to 15 years from randomisation
2. To determine the optimum age for the examination, measured at 10 and 11 years
3. To assess acceptability and organisational impact (evaluated in the recruitment phase)

**Overall study start date**

01/10/1995

**Completion date**

30/06/1998

## **Eligibility**

**Key inclusion criteria**

Eligible, interested respondents to a mail questionnaire sent to a random population sample of men and women aged 55 to 64 years.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40,000

**Total final enrolment**

34272

**Key exclusion criteria**

1. Personal history of colorectal cancer, adenomas, inflammatory bowel disease, recent colorectal endoscopy
2. Subjects mentioning two first-degree relatives with colorectal cancer
3. Subjects unable to give informed consent

**Date of first enrolment**

01/10/1995

**Date of final enrolment**

30/06/1998

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

Via S Francesco da Paola 31

Turin

Italy

10123

## **Sponsor information**

**Organisation**

Italian Association for Cancer Research (Associazione Italiana per la Ricerca sul Cancro [AIRC])  
(Italy)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.airc.it>

**ROR**

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

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Support for the study was provided by grants from:

**Funder Name**

Italian Association for Cancer Research (Associazione Italiana per la Ricerca sul Cancro [AIRC]) (Italy)

**Funder Name**

Italian National Research Council (CNR) (Italy) (ref: 95.00539.PF39, 96.00736.PF39)

**Funder Name**

The following provided additional resources for the implementation of the study in Rimini, Biella, Milano and Torino, respectively:

**Funder Name**

Romagnolo Cancer Institute (Istituto Oncologico Romagnolo [IOR]) (Italy)

**Funder Name**

Edo Tempia Fund (Fondo Edo Tempia) (Italy)

**Funder Name**

University of Milan (Università degli Studi di Milano) (Italy)

## Funder Name

Local Health Unit (Azienda Sanitaria Locale [ASL]) 1, Torino (Italy)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### 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="#">Other publications</a>	baseline findings	04/12/2002		Yes	No
<a href="#">Results article</a>		09/11/2021	10/11/2021	Yes	No