

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

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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?
Results article		09/11/2021	10/11/2021	Yes	No
Other publications	baseline findings	04/12/2002		Yes	No