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

Submission date 10/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/12/2010	**Overall study status** Completed	
Last Edited 10/11/2021	**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
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
Via Corridoni 7
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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?
Other publications	baseline findings	04/12/2002		Yes	No
Results article		09/11/2021	10/11/2021	Yes	No