ISRCTN83029072 https://doi.org/10.1186/ISRCTN83029072

Trying to improve the compliance to colorectal cancer screening: type of test provider (GP versus hospital) and type of faecal occult blood test (Guaiac versus immunochemical)

Submission date
05/09/2005

Registration date
09/09/2005

Last Edited
15/01/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study objectives
The efficacy of colorectal cancer screening (CRCS) using faecal occult blood test (FOBT) in reducing colorectal cancer (CRC) mortality in a population at generic risk, has been shown in several large randomized trials.

The screening programs need to contact the whole target population and involve as many people as possible in order to be actually effective. The scientific literature about the reasons for non-compliance have generated few definitive operational recommendations.

Two types of FOBT are now available: the Guaiac and the Immunochemical test. The sensitivity and specificity of the two tests are similar and do not clearly indicate which one is better for screening. The price of the immunochemical test is actually about 1.5 times higher than the Guaiac, but there are no data about the costs per person screened. The Guaiac test recommends three different evacuations, and requires the patient to store the samples, and follow dietary restrictions. The immunochemical test is recommended on a single evacuation and does not require dietary restrictions. The discomfort and embarrassment of faecal sampling and the dietary restrictions have been hypothesized to be determinants of non-compliance. This background may determine lower compliance to the Guaiac test.

Several guidelines for screening programme implementation recommend the involvement of general practitioners (GP) and family practitioners (FP); nevertheless the role of the GPs and FPs varies between countries and health service organizations, making this recommendation hard to implement. The Agency for Public Health of Lazio, Italy, decided to design a trial phase in order to plan an evidence-based implementation of the CRCS program. The aim of this approach is to guarantee that the efficacy of CRCS can be translated to effectiveness in a public health intervention. The screening strategy adopted was: yearly FOB testing for 5074 year olds and, for positives, colonoscopy. A special focus was how to obtain a high compliance to screening; the topics studied were: GPs attitudes and practices, type of FOBT, test provider, and the individual reasons.

Studies included: a survey, a randomized factorial trial nested in the survey, and a casecontrol study nested in the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Faecal occult blood test:
Two types of test: guaiac versus immunochemical
Two types of provider: General Practitioner versus Hospital gastroenterology centre

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Compliance to screening: (number of returned faeces samples)/(total number of invited subjects)

Secondary outcome measures
Positivity rate; variability of the positivity rate; rate of inadequate samples; positive predictive value.

Overall study start date
01/10/2002

Completion date
30/04/2003

Eligibility

Key inclusion criteria
We selected 13 hospitals, out of 20 to participate in the screening programme, in order to represent all types of gastroenterology units (5 university hospitals, 2 large research hospitals, 6 local hospitals) and all geographic areas (7 in the metropolitan area of Rome, 2 in the outskirts of Rome, 4 in towns and small cities of the province). We included in a survey about screening attitudes all the GPs with an office in the 13 selected hospital districts. During the survey, all the

GPs were asked to participate in a trial to evaluate the best strategies to enhance the compliance to CRCS. The conditions for eligibility of the GPs were: more than 100 people aged 50 74 in the practice population; a personal computer in the office; and consent to participate.

For each of the 13 districts we sampled 10 eligible GPs. The sampled GPs, primary sampling units, were randomised as follows: for each district, five to the immunochemical test and five to the Guaiac test. We sampled 2/10 of the target practice population for each GP; 1/10 of the population was randomised to the GP arm and 1/10 to the hospital arm.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
We randomised 7320 subjects

Key exclusion criteria
We analysed the lists of randomised patients: the second member of a pair with the same telephone number was rejected and substituted, if assigned to a different arm.

Date of first enrolment
01/10/2002

Date of final enrolment
30/04/2003

Locations

Countries of recruitment
Italy

Study participating centre
Agency for Public Health, Lazio Region
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Sponsor information

Organisation

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
The study is funded exclusively by the Agency for Public Health of the Lazio Region (Italy)

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	Cluster results	01/02/2005		Yes	No
Other publications	Study design	01/06/2005		Yes	No
Other publications	Survey	01/07/2005		Yes	No
Results article	Case controlled study results	01/12/2005		Yes	No

Results article	Results	01/02/2006	Yes	No