

Mailing of the Faecal Occult Blood Test (FOBT) to increase compliance to colorectal cancer screening and to reduce costs

Submission date 08/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/12/2020	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

Study information

Scientific Title
Effect of mailing of the Faecal Occult Blood Test (FOBT) on compliance to colorectal cancer screening and on front office costs: a randomised controlled trial

Acronym

FOBT postale

Study objectives

European Commission Guidelines on cancer prevention recommend to the member states the implementation of colorectal cancer screening programmes based on the Faecal Occult Blood Test (FOBT) every two years in the population 50-70 years old. In Italy, colorectal cancer screening is affected by low compliance. Furthermore the front office activities to give the faecal sampler to the participants are time and cost consuming. A direct mailing strategy of the faecal sampler could increase compliance and could reduce the resource consumption of the front office activities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval is not required as this study involves only service provision that is already recommended by the European Commission.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Compliance to colorectal cancer screening

Interventions

The trial is recruiting at the following four centres: Viterbo, Latina, Firenze, Abruzzo

Group 1: Participants randomised to either direct mailing of the FOBT or re-call letter

Group 2: Participants randomised to either direct mailing of the FOBT or invitation letter

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Compliance to screening at 60 days after mailing (of the FOBT or of the letter).

Key secondary outcome(s)

Costs of mailing compared to front office.

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Group 1 (non responders): all the target population (both males and females, age 50-70) invited for a new round of screening and who did not responded to the first invitation letter and is eligible for a re-call letter.

Group 2 (responders to previous screening): all the people who responded to the previous screening round (both males and females, age 52-70) and are eligible for being invited to a new screening round

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

7415

Key exclusion criteria

Group 1: None

Group 2: A previous positive test including FOBT, flexosigmoidoscopy and colonoscopy

Date of first enrolment

01/03/2009

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Italy

Study participating centre

Laziosanità - Agenzia di Sanità Pubblica

Rome

Italy

00198

Sponsor information

Organisation

Ministry of Health, Centre for Diseases Prevention amd Control (Italy)

ROR

<https://ror.org/00svmjx28>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health, Centre for Diseases Prevention amd Control (Italy)

Results and Publications

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	01/09/2011	29/12/2020	Yes	No