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

Submission date	Recruitment status	[_] Prospectively registered
08/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/12/2020	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Paolo Giorgi Rossi

Contact details
Laziosanità - Agenzia di Sanità Pubblica
Via di S. Costanza 53
Rome
Italy
00198
+39 (0)683060438
giorgirossi@asplazio.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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

Secondary outcome measures
Costs of mailing compared to front office.

Overall study start date
01/03/2009

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

Age group
Adult

Sex
Both

Target number of participants
Group 1: 2,700; Group 2: 2,100

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)

Sponsor details
Viale Giorgio Ribotta, 5
Rome
Italy
00144
-
an.federici@sanita.it

Sponsor type
Government

Website
http://www.ccm-network.it

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

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