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PARC (Promoting Adhesion to Referral for Colonoscopy) study: to compare different ways to invite subjects with a positive fecal occult blood test to colonoscopy

Submission date
28/08/2013

Recruitment status
No longer recruiting

Registration date
30/09/2013

Overall study status
Completed

Last Edited
12/05/2014

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We carried out a study on subjects with a positive fecal occult blood test performed in the local colorectal cancer screening programme. Our goal was to find the best way to invite these subjects to undergo a total colonoscopy (TC).

Who can participate?
3800 subjects aged 50-69 years old, who attended nine colorectal cancer screening programmes in Italy.

What does the study involve?
The screening programmes invited subjects to undergo a fecal occult blood test (FOBT) every two years. Subjects with a positive FOBT (FOBT+) were invited to undergo a TC. During the study, FOBT+ subjects were randomly allocated to be invited to a TC in different ways:
1. Both first invitation and recall by mail
2. First invitation by phone, recall to non-compliers by mail
3. First invitation by phone, recall by face-to-face counseling with the General Practitioner
4. First invitation by phone, recall by an appointment with a specialist screening practitioner (nurse, healthcare assistant)
At the end of the study, we compared the uptake of TC of the groups of subjects who had received the different types of invitation.

What are the possible benefits and risks of participating?
Some of participants will receive a better method of invitation to a TC than the usual care of their local screening programme.
There will be no risks for those who participate in the study.

Where is the study run from?
The study was carried out by the Italian screening programmes of Belluno, Este (PD), Torino, Firenze, Lucca, Ferrara, Forlì, Perugia and Latina.

When is the study starting and how long is it expected to run for?
The study started in September 2010 and ran until March 2012.

Who is funding the study?
Italian Ministry of Health.

Who is the main contact?
Dr Manuel Zorzi

Contact information

Type(s)
Scientific

Contact name
Dr Manuel Zorzi

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RTV-2010-CCR-01

Study information

Scientific Title
PARC (Promoting Adhesion to Referral for Colonoscopy) study: to compare different ways to invite subjects with a positive fecal occult blood test to colonoscopy an open, randomised, parallel group trial

Acronym
PARC

Study objectives
We compare the performances of different ways to invite subjects with a positive fecal occult blood test (FOBT+) to a total colonoscopy: mail vs phone call for the first invitation and mail vs counseling with the General Practitioner vs appointment with a specialist screening practitioner for recall of non compliers to first invitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not required as the study involved the use of different ways to invite people to a total colonoscopy, which are already currently used in the context of ongoing regional screening programmes, independently on their proven efficacy.
Furthermore, the nature of the intervention did not require obtaining informed consent by participants in the study.

Study design
Open randomised parallel group multi-site trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Colorectal cancer screening programmes

Interventions
Subjects with a positive fecal occult blood test are randomized to be invited to a total colonoscopy in different ways:
1. Both first invitation and recall by mail
2. First invitation by phone, recall to non compliers by mail
3. First invitation by phone, recall by face-to-face counseling with the General Practitioner
4. First invitation by phone, recall by an appointment with a specialist screening practitioner (nurse, healthcare assistant)

The intervention is instantaneous: the subject is invited to a colonoscopy and we record whether the subject complies or not. Non-compliers to invitation are recalled within two months after

first invitation. The follow-up lasts three further months in order to collect the information about late compliers. After three months, non-compliers were interviewed to find out whether they had undergone colonoscopy in a service outside the screening programme.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Compliance to the two methods of first invitation to a total colonoscopy: measured at the baseline
2. Compliance to the three methods of recall of non-compliers: measured after three months
Both outcomes are recorded by the endoscopist (or the nurse of the endoscopy service) through the management software of the screening programme.

Secondary outcome measures
Assessed three months after recruitment:
Uptake of total colonoscopy outside the endoscopy services adhering to the screening programme

Overall study start date
01/09/2010

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Subjects (male and female) 50-69 years old invited to perform a fecal occult blood test by the local colorectal cancer screening programme
2. With a positive fecal occult blood test

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3,750

Key exclusion criteria
Subjects who did not give the consent to inform their General Practitioner of the result of the fecal occult blood test

Date of first enrolment
01/09/2010

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
Italy

Study participating centre
Registro Tumori del Veneto
Padova
Italy
35131

Sponsor information

Organisation
Italian Ministry of Health (Italy)

Sponsor details
Agenzia Sanitaria Regionale Abruzzo
via Attilio Monti, 9
Pescara
Italy
65127

Sponsor type
Government

ROR
https://ror.org/00789fa95

Funder(s)

Funder type
Government

Funder Name

Italian Ministry of Health (IT) (Italy) (ref: (Prot. n. 2015 del 24/07/2009 ASR Abruzzo)

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	01/08/2014		Yes	No