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Assessing the impact of a new fit test in the context of a population based organized screening programme for colorectal cancer

Submission date	Recruitment status	[_] Prospectively registered
03/05/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/05/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/03/2018	Cancer	

Plain English summary of protocol

Background and study aims
Colorectal, or bowel cancer, is very common. However, if detected at an early stage, it can be easier to treat and led to a much better chance of survival. The fecal immunochemical test (FIT) is a screening test for bowel cancer that tests for hidden blood in the stool. Blood in the stool can be an early sign of the disease. This study is investigating a new FIT screening test called FIT HM-Jackarc. It compares how this test performs against the test that is in routine use (FIT OC-Sensor Diana).

Who can participate?
Adults aged between 50-75.

What does the study involve?
Participants are randomly allocated to one of two groups. One group is screened for colorectal cancer using FIT HM-Jackarc. The other group is screened for colorectal cancer using FIT OC-Sensor Diana.
All participants from both groups receive an invitation kit though the post. This includes a consent form for them to sign and a leaflet describing the study. They are asked to store their stool sample at
4°C and send it back to the laboratory using the pre-paid envelope provided. The analyses are performed by experienced laboratory medicine professionals. Participants found to have hidden blood in their stool undergo a colonoscopy (a procedure where a camera is used to look at the inside of the bowel).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Screening Laboratory, Umbria Region, Perugia (Italy)

When is the study starting and how long is it expected to run for?
February 2014 to December 2015

Who is funding the study?
1. A Menarini Diagnostics (Italy)
2. Kyjowa Medex Co.,Ltd (Japan)

Who is the main contact?
1. Dr Morena Malaspina (scientific)
morena.malaspina@uslumbria1.it
2. Dr Basilio Ubaldo Passamonti (scientific)
basilio.passamonti@uslumbria1.it

Contact information

Type(s)
Scientific

Contact name
Dr Morena Malaspina

Contact details
via Gaetano Donizetti 75
Perugia
Italy
06132
3285811564
morena.malaspina@uslumbria1.it

Type(s)
Scientific

Contact name
Dr Basilio Ubaldo Passamonti

Contact details
via Pietro Mascagni 31/B
Perugia
Italy
06132
3482504598
basilio.passamonti@uslumbria1.it

Additional identifiers

Protocol serial number
460

Study information

Scientific Title
Assessing the impact of a new fit test in the context of a population based organized screening programme for colorectal cancer: a comparative effectiveness trial

Study objectives
The aim of this study is to compare the performances of two fecal immunochemical tests

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Healthcare Company, 29/04/2014, ref: 3032/14/AV Registration n. 2289/14

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
During the enrolment period (from 06 November 6th, 2014 to 31 March 2015), all the eligible population were randomly allocated (ratio 1:1) to be screened with two fecal immunochemical test (FIT) systems, namely:

1. OC-Sensor
2. HM- JACKarc

The randomisation was stratified by gender, age group (50-59/60-74 years), screening history (first/subsequent screening) and area of residence (urban/rural). The scheme was computer generated within the screening programme IT system which governs the screening programmes and identifies when individuals are to be invited to participate. The process of generating and mailing the different invitation materials was fully automated, therefore blinding the researchers to the allocation of the intervention to individuals. A reminder letter was mailed to all non-responders three months following the initial invitation.

The invitation kit mailed for the study included an informed consent form and a leaflet explaining the design and the rationale for the study. The invitation materials were designed to be as similar as possible for each both of the analytical systems. Participants were instructed to store the sample at 4°C. and to send back the sample device to the central laboratory, using the pre-paid envelope included in the invitation kit, as soon as possible. Devices were collected and forwarded to the screening laboratory every 24 hours day by the mail postal company, following the routine procedures usually adopted in of the screening programme. All the exams were processed and analyses were performed in the central laboratory of the Umbria screening programme by three experienced laboratory medicine professionals. Participants with positive results from FIT (20 µg Hb/gr faeces) were underwent colonoscopy. Histology was defined

according to the World Health Organization criteria. Advanced adenoma (AA) was defined as an adenoma with any of the following features: size ≥ 10 mm, high-grade dysplasia, or villous component >20%. Cancer was defined as the invasion of malignant cells beyond the muscularis mucosae.

Intervention Type
Device

Primary outcome(s)
Participation rate, measured at 6 months since the invitation, as the proportion of those performing the test of those invited

Key secondary outcome(s))
1. Proportion of inadequate tests: measured at the end of the study, as the proportion of samples with inadequate material for the analysis. Laboratory assessment
2. Positivity rate: measured at the end of the study, as the proportion of samples with Hb level above the stipyulated cut-off value (100 ng/ml buffer) over the total number of adequate tests. Laboratory assessment
3. Positive predictive value (PPV): mesasured at the end of the study, as the proportion of subjects detected with a CRC or advanced adenoma over those ubdergoring colonscopy assessment
4. Detection rate (DR) for advanced adenoma and CRC: mesasured at the end of the study, as the proportion of subjects detected with a CRC or advanced adenoma over those who have perfromed the FIT test
5. Number needed to scope (NNScope) to detect one advanced neoplasm (AN: advanced adenoma + CRC):mesasured at the end of the study, as 1/PPV

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Men and women
2. Age ranged 50-74 years
3. Resident in Umbria Region
4. Without personal history of colorectal cancer

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Personal history of colorectal cancer
2. Participants undergone tests for fecal blood within 2 years
3. Participants undergone sigmoidoscopy or colonoscopy within 5 years

Date of first enrolment
06/11/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Italy

Study participating centre
Screening Laboratory, Umbria Region (Laboratorio Unico di Screening Regione Umbria)
Via XIV settembre 75
Perugia
Italy
06124

Sponsor information

Organisation
Umbria Region: Prevention, veterinary and food safety

Funder(s)

Funder type
Industry

Funder Name
A Menarini Diagnostics (Italy)

Funder Name
Kyjowa Medex Co.,Ltd (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018		Yes	No