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Assessing the additional benefit of an innovative imaging system for colonoscopy

Submission date
17/09/2015

Recruitment status
No longer recruiting

Registration date
18/09/2015

Overall study status
Completed

Last Edited
04/02/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
A colonoscopy is an important procedure in which a narrow, flexible, telescopic camera is inserted into the back passage to look at the lining of the large bowel. Although it can be an uncomfortable procedure, it is the most effective way to diagnose colorectal cancer (bowel cancer). Although colonoscopies are very effective at finding tumours (neoplasms), it is reported that they do not always spot polyps. A polyp is a very small growth on the inner lining of the colon or rectum. Although most colorectal polyps do not become cancerous, almost all cases of colorectal cancer begin as polyps. It is therefore very important to detect polyps, as their presence increases the risk of colorectal cancer. A possible reason that polyps are sometimes missed in colonoscopies may be because of inadequate equipment. A full spectrum endoscope (FUSE) is a device that has been developed to help lower the miss rate of polyps in routine colonoscopies. The device uses three cameras to give a panoramic view of the colon, allowing for a more complete picture of the colon. The aim of this study is to find out how well this new technology performs in comparison to the standard device used.

Who can participate?
Adults between 50 and 69 years of age, having their first colonoscopy after testing positively for blood in their stool in a mass screening programme.

What does the study involve?
Participants are randomly allocated in one of two groups. For participants in the first group, the colonoscopy procedure is completed using a standard forward-viewing colonoscopy. For participants in the second group, the procedure is completed using full spectrum endoscopy (FUSE). After the procedures, the accuracy of the two devices is compared. Participants also are asked to complete a questionnaire after the procedure about their experiences.

What are the possible benefits and risks of participating?
A potential benefit for participants in the FUSE group is that the procedure may reveal polyps that otherwise might have been missed. There are no risks of participating other than the standard risks involved with having a colonoscopy. Additionally, some additional polyps

detected with the new instrument might not be clinically significant.
Where is the study run from?
Seven hospitals in Italy.

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

Who is funding the study?
Regional Health Authority, Piedmont Region (Italy)

Who is the main contact?
Dr Carlo Senore
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
351

Study information

Scientific Title
Assessing the additional neoplasia yield of FUll Spectrum Endoscopy in a CRC screening setting

Acronym
FUSE

Study objectives

The use of an instrument ensuring a wider view of the colonic mucosa would result in a higher rate of detection of significant colonic lesions as compared to standard instruments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comitato etico interaziendale AOU Città della Salute e della Scienza, 26/05/2014, ref: N 531

Study design
Multi-centre stratified randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
1. Colorectal cancer
2. Colorectal adenomas

Interventions
Patients are randomly allocated into two groups, who will each undergo a colonoscopy. For patients in the first group, a standard white light HD endoscope (Standard Forward View) is used, and for patients in the second group, Full Spectrum Endoscopy (FUSE) technology is used. The two instruments are similar, the only difference being related to the characteristics and number of the lenses. The only difference for the patients might be related to the slightly longer duration of the exam with FUSE technology as it may be more likely to find one or more polyps. IN general a colonscopy is expected to last about 30 minutes. No study related follow-up after the completion of the colonoscopic assessment is planned within this study

Intervention Type
Device

Primary outcome measure
1. Additional yield of advanced adenomas in patients when using Fuse as compared to SFV
2. Proportion of patients detected with 3 or more adenomas when using Fuse as compared to SFV

Secondary outcome measures
1. Overall adenoma and polyp detection rate, flat adenoma and serrated polyps/adenomas detection rate of the two techniques, determined from the information recorded in endoscopist

and pathology reports
2. Comparison of the size of multiple lesions detected by the two methods, determined from the information recorded in endoscopist and pathology reports
3. Comparison of the detection rate of neoplasia by colonic site: distal (rectum, sigmoid and descending colon) and proximal (proximal to the descending colon), determined from the information recorded in endoscopist and pathology reports
4. Differences in the surveillance guidelines post-colonoscopy when comparing the two arms, determined from the information recorded in endoscopist and pathology reports
5. Comparison of the time required to reach the cecum, determined from the information recorded in endoscopist and pathology reports
6. Comparison of the withdrawal and total procedure time, determined from the information recorded in endoscopist and pathology reports
7. Assessing the learning curve of participating endoscopists, determined from the information recorded in endoscopist and pathology reports
8. Assessing patient's experience, measured using a questionnaire administered at the end of the examination
9. Assessing the specific contribution of the additional view estimating the proportion of polyps detected using the additional views only, determined from the information recorded in endoscopist and pathology reports

Overall study start date
01/03/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Consecutive patients aged 50 to 69 years undergoing their first colonoscopy examination in the participating centers following a positive fecal immunochemical test (FIT) performed in the context of a regional mass-screening program.

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
Patients aged 50 to 69 undergoing their first colonoscopy examination in the participating centers following a positive fecal immunochemical test (FIT) performed in the context of a regional mass-screening program. The target sample size is 350 patients per arm

Key exclusion criteria
1. Personal history of colorectal cancer or advanced adenoma
2. More than one first degree relative with colorectal cancer

3. Inflammatory bowel disease (IBD)
4. Endoscopy within past 5 years

Date of first enrolment
01/09/2014

Date of final enrolment
15/10/2015

Locations

Countries of recruitment
Italy

Study participating centre
CPO Piemonte and Gastroenterology Unit 2 - AOU Città della Salute e della Scienza
Via S Francesco da Paola 31
Turin
Italy
10123

Study participating centre
Ospedale Valduce
Como
Italy
22100

Study participating centre
Istituto Clinico Humanitas
Rozzano (Milano)
Italy
20089

Study participating centre
Ospedale di Circolo
Rho (Milano)
Italy
20017

Study participating centre

Ospedale S Chiara
Trento
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IRCCS Ospedale S. Maria Nuova
Reggio Emilia
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Study participating centre
Osepdale Nuovo Regina Margherita
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Sponsor information

Organisation
CPO Piemonte

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Sponsor type
Government

ROR
https://ror.org/05v0e5774

Funder(s)

Funder type
Government

Funder Name

Regional Health Authority, Piedmont Region (Italy)

Results and Publications

Publication and dissemination plan
A report to be submitted to a scientific journal, and preliminary results will be presented in the context of the next UEGW in Barcelona in October 2015.

Intention to publish date
31/10/2015

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	01/11/2017		Yes	No