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Comparing two optical technologies when screening for bowel cancer: a trial from several UK hospitals

Submission date
29/09/2018

Recruitment status
No longer recruiting

Registration date
16/10/2018

Overall study status
Completed

Last Edited
18/07/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The UK bowel cancer screening program has been set up to help detect bowel cancer offering colonoscopy to patients having a positive faecal occult blood test, which is a test that detects blood in someone's stools. Colonoscopy is the gold standard tool for finding bowel cancer and polyps (type of growth that sticks up out of tissue) or adenomas (non-cancerous tumours). High quality colonoscopy largely depends on quality procedures and skills of the operator, which can vary extensively. Olympus and Pentax are two frequently used colonoscopy technologies in the UK. Although both use the same principle of video endoscopy, each type of instrument has different features that allow the operators the best options for manoeuvres and correctness, allowing for more certainty in diagnosis and better patient comfort. This study aims to compare these two optical technologies (standard definition Olympus Lucera (SD-OL) with Scope Guide against the high definition Pentax HiLine (HD-PHL)) when screening for bowel cancer in a randomised controlled trial from several UK hospitals.

Who can participate?
Adults who tested positive on a faecal occult blood test and were scheduled to undergo a first colonoscopy as part of National bowel cancer screening program.

What does the study involve?
Patients will be allocated randomly to either of the optical technologies under comparison (SD-OL vs HD-PHL). Then patients' notes will be reviewed by the research team to record the frequency of detecting polyps and adenomas as well as procedural information, such as length of procedure, patient comfort, and type and dosage of medication used to make patients drowse or sleepy.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but there should be benefits to future patients undergoing a first colonoscopy during the national bowel cancer screening

program because the results of the study are likely to influence which optical technology is best to be used to help detect bowel cancer. The risks of participation are those normally associated with standard care colonoscopy, which are most commonly abdominal pain or cramping.

Where is the study run from?
1. University College Hospital, London (UK) (lead centre)
2. University Hospital Llandough, Cardiff (UK)
3. Bradford Hospital, Bradford (UK)
4. Addenbrooke's Hospital, Cambridge (UK)

When is the study starting and how long is it expected to run for?
January 2011 to May 2014

Who is funding the study?
Self-funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11/LO/1712

Study information

Scientific Title
A randomised controlled trial to compare two optical technologies in colorectal cancer screening: a multi-site evaluation

Study objectives
This is a prospective randomised controlled trial to compare Olympus Lucera and Pentax HiLine colonoscopy systems at multiple sites where the National Bowel Cancer Screening Program is being undertaken. From preliminary literature searches, such a study comparing these two colonoscope models has yet to be performed. The main purpose of this analysis is to see if any one system appears to be superior when comparing defined parameters for colonoscopies performed as part of the bowel cancer screening program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London Central, 07/11/2011, REC ref: 11/LO/1712

Primary study design
Interventional

Study design
Interventional prospective multi-centre randomised controlled trial

Study type(s)
Diagnostic

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

Interventions
For randomisation, every potential participant was consecutively allocated to the next available slot during the BCS pre-assessment pathway. Each study site had both Olympus Lucera and Pentax HiLine colonoscopes available. The available slots were in either an Olympus Lucera (arm 1) or Pentax HiLine system (arm 2) list. The person performing allocation was not aware of the system in place for that specific list in order to minimise selection bias. For operational reasons, the entire endoscopy list was run with a single type of endoscope. Therefore, randomisation was on an endoscopy list basis rather than an individual patient basis and was stratified by the endoscopist (list/block randomisation). This passive randomisation ensured balance to operators and approximately equal numbers in each arm.
Arm 1 received a colonoscopy with the Standard Resolution Olympus Lucera System (SD-OL). This is a white balance colonoscope using enhancement level 2. Narrow band imaging was used at the discretion of the endoscopist, but this was recorded. Use of scope guide was allowed and recorded at the endoscopist's discretion.
Arm 2 received a colonoscopy with the High Resolution Pentax HiLine System (HD-PHL). This is a white balance colonoscope. I-scan 1 was used during withdrawal from the caecum and I-scan 2 & 3 were used at the discretion of the endoscopist but this was recorded.
The duration of treatment was the length of the colonoscopy and all participants received standard follow-up care for colonoscopies.

Intervention Type
Procedure/Surgery

Primary outcome(s)

The following were measured as categorical variables with two outcomes (yes/no) and reported as a percentage. These were assessed using a review of histopathology reports, endoscopy images and endoscopy reports at the baseline (after the colonoscopy):
1. Total polyp detection rate (PDR)
2. Adenoma detection rate (ADR)

Key secondary outcome(s)
The following were assessed through a review of endoscopy images, endoscopy reports and patient notes (unless otherwise stated) at the baseline (after the colonoscopy):
1. Caecal intubation time, measured in minutes
2. Caecal intubation rate, measured as a categorical variable with two outcomes (yes/no) and reported as a percentage
3. Total procedure time, measured in minutes
4. Withdrawal time, measured in minutes
5. Patient comfort scores, measured with a Global Rating Scale with a score of 1 indicating "no discomfort" and a score of 5 indicating "severe discomfort"
6. Sedation used, measured through recording medication used and the dose given (percentages of each medication and mean dose with standard deviation were calculated)
7. Polyp retrieval rate, measured as a categorical variable with two outcomes (yes/no) and reported as a percentage
8. Immediate/late complications, measured as a percentage for each complication
9. Endoscopists' comments on procedural difficulty, recorded with free text by the endoscopist

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Positive faecal occult blood test
2. Scheduled to undergo first (index) colonoscopy as part of the National BCS program
3. Undergoing colonoscopy at any one of:
3.1. University College Hospital (London)
3.2. University Hospital Llandough (Cardiff)
3.3. Bradford Hospital (Bradford)
4. Aged 18 years or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Total final enrolment
262

Key exclusion criteria
1. Contraindications to colonoscopy
2. Follow-up (surveillance) patients

Date of first enrolment
01/05/2012

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
University College London Hospitals NHS Foundation Trust
GI Services
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Cardiff & Vale University Health Board, University Hospital Llandough
Penlan Road, Penarth
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CF64 2XX

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Department of Gastroenterology
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Other

Funder Name
Investigator Initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2019	18/07/2019	Yes	No
Plain English results			21/05/2019	No	Yes