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Randomised controlled trial of narrow band imaging (NBI) versus standard endoscopy for adenoma detection

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 02/10/2014	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0515176146

Study information

Scientific Title

Study objectives
Does a new colonoscopic viewing technique called narrow band imaging (NBI) help doctors detect more patients with at least one pre-cancerous polyp (adenoma) than conventional colonoscopy using white light alone?
The study is to determine if narrow band imaging is better for detecting flat polyps than conventional diagnosis. A high detection rate of flat polyps would indicate that this type of surveillance should be used in the national cancer screening programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Surgery: Colonoscopy

Interventions
Narrow band imaging (NBI) versus standard endoscopy.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Categorical data will be compared with chi-squared test, t-testing on Mann-Whitney U test will be used for continuous data depending on normality

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Patients over 18 assessed as fit for routine colonoscopy
2. Patients attending for screening or surveillance colonoscopy
3. At least three adenomas or one adenoma >10 mm at previous colonoscopy post colorectal cancer resection screening with positive faecal occult blood tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
Pre-intubation:
1. Patients with known colitis or polyposis syndromes
2. Unable or unwilling to give consent

Pre-caecum to randomisation:
1. Those with poor bowel preparation
2. Unable to reach caecum due to stricture

Date of first enrolment
20/01/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Wolfson Unit 2nd Floor
Harrow
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
North West London Hospitals NHS Trust (UK)

Results and Publications

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	01/11/2012		Yes	No