ISRCTN36386665 https://doi.org/10.1186/ISRCTN36386665

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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Brian P Saunders

**Contact details**
The Wolfson Unit 2nd Floor
North West London Hospitals NHS Trust
St Mark's Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ
+44 (0)20 8235 4225
b.saunders@imperial.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### 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
Surgery: Colonoscopy

### Interventions
Narrow band imaging (NBI) versus standard endoscopy.

### Intervention Type
Procedure/Surgery

### Phase
Not Applicable

### Primary outcome measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
20/01/2006

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
107 patients will be needed for each group, 214 in total. Recruitment completed Summer 2008

### 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**
England

United Kingdom

**Study participating centre**
**The Wolfson Unit 2nd Floor**
Harrow
United Kingdom
HA1 3UJ

# Sponsor information

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

**Sponsor details**
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
North West London Hospitals NHS Trust (UK)

# 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 | 01/11/2012 | | Yes | No |