

# Randomised controlled trial of Narrow Band imaging with magnification (NBI) versus white light endoscopy for dysplasia detection in ulcerative colitis surveillance

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/09/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**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  
+44 020 8235 4225  
b.saunders@imperial.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0515176147

## **Study information**

### **Scientific Title**

Randomised controlled trial of Narrow Band imaging with magnification (NBI) versus white light endoscopy for dysplasia detection in ulcerative colitis surveillance

### **Study objectives**

Does a new colonoscopic viewing technique called narrow band imaging (NBI) help doctors detect more patients with at least pre-cancerous area (dysplasia associated lesion or mass, DALMs) than conventional colonoscopy using white light alone?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Added 17 July 2008: approval granted by Harrow Research Ethics Committee REC 06/Q0408/10

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Diagnostic

### **Participant information sheet**

Not available in web format; for printed version please contact the investigators at the address below

### **Health condition(s) or problem(s) studied**

Digestive System: Ulcerative colitis

### **Interventions**

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.

### **Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

The study is to determine if the use of a narrow band of light can help detect more pre-cancerous or cancerous areas than the normal white light used for detection. The outcome measure is to determine the numbers of patients with at least one cancer in either group.

**Secondary outcome measures**

Added 17 July 2008:

1. Are more precancerous lesions found in total with NBI?
2. Are more advanced precancerous lesions found with NBI?
3. Are more patients found with more than one precancerous lesion with NBI?
4. How many lesions are successfully completely removed with endoscope?

**Overall study start date**

01/03/2006

**Completion date**

31/12/2008

**Eligibility****Key inclusion criteria**

1. Patients with longstanding extensive colitis, with evidence of microscopic inflammation at a previous colonoscopy
2. Patients over 18

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

110 patients will be needed for each group, 220 in total

**Key exclusion criteria**

Pre-intubation:

1. Pregnant patients
2. Severe active colitis
3. Those unwilling or unable to give consent

Pre-randomisation:

1. Those with poor bowel preparations
2. Unable to reach caecum due to stricture

**Date of first enrolment**

01/03/2006

**Date of final enrolment**

31/12/2008

## **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

**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?
<a href="#">Other publications</a>	case report	01/10/2006		Yes	No
<a href="#">Results article</a>	results	01/06/2012		Yes	No