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

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
14/09/2017

Condition category
Digestive System

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

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s)
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?

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

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
United Kingdom

England

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

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	01/06/2012		Yes	No
Other publications	case report	01/10/2006		Yes	No