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The use of methylene blue dye in the diagnosis of dysplasia in Barrett's Oesophagus Surveillance

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 12/02/2010	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436121390

Study information

Scientific Title

Study objectives
The purpose of this study is to compare the use of MB directed biopsies (MBDB) to random biopsies (RB) in the diagnosis of dysplasia.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Digestive System: Dysplasia

Interventions
1. Methylene blue directed biopsies
2. Random biopsies

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The frequency of dysplasia between methylene blue directed biopsies and random biopsies.

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/01/2003

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Barrett's oesophagus patients with recent diagnosis of dysplasia

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Room 190A, Gastroenterology Department
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching 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	01/08/2006		Yes	No