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

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|---|---|---|
| **Submission date**<br>12/09/2003 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>12/09/2003 | **Overall study status**<br>Completed | |
| **Last Edited**<br>12/02/2010 | **Condition category**<br>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**
Leeds
United Kingdom
LS1 3EX

# Sponsor information

### Organisation
Department of Health (UK)

### Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

### 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 |