ISRCTN15254497 https://doi.org/10.1186/ISRCTN15254497

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

Contact name
Dr CH Lim

Contact details
Room 190A, Gastroenterology Department
Clarendon Wing
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
The frequency of dysplasia between methylene blue directed biopsies and random biopsies.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/01/2006

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Room 190A, Gastroenterology Department
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching 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	01/08/2006		Yes	No