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A comparison of autofluorescence bronchoscopy and videobronchoscopy for the detection of precancerous lesions in patients with suspected lung cancer

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 20/08/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pallav Shah

Contact details
Royal Brompton & Harefield NHS Trust
Sydney Street
London
United Kingdom
SW3 6NP
+44 020 7351 8021
pallav.shah@ic.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0201171075

Study information

Scientific Title

Study objectives
The objective of the current study is to assess the accuracy of and correlation between the fluorescence bronchoscopy findings and the pathological findings in the patients with suspected lung cancer in comparison to videobronchoscopy.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer: Lung

Interventions
The patient will first have a videobronchoscopy and any changes classified as normal, inflammatory changes, or suspicious. Images will be systematically captured and stored of the full endobronchial tree. The examination will then be repeated in the fluorescence mode and green fluorescence classified as normal the bluish area classified as inflammation and the magenta as suspicious. Biopsy samples will be obtained from all areas of inflammation and two areas of normal appearance. The site of biopsy will be documented but the pathologists will remind blinded to the bronchoscopy findings.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
We therefore plan to study 100 patients and will calculate the relative sensitivity, specificity and accuracy of videobronchoscopy compared to that of fluorescence bronchoscopy.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
50 patients in year 1 and 50 patients in year 2. Total 100.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton & Harefield NHS Trust
London
United Kingdom
SW3 6NP

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
Royal Brompton and Harefield NHS Trust (UK)

Funder Name
No External Funding. NHS R&D Support Funding

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	01/05/2010		Yes	No