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A randomised, controlled trial of surgical staging with endobronchial and endoscopic ultrasound for assessment of the mediastinum in lung cancer

Submission date
13/06/2007

Recruitment status
No longer recruiting

Registration date
14/06/2007

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Before undergoing surgery for lung cancer it is crucial to know if the cancer has spread to the lymph nodes in the chest. Currently this is assessed by an operation called a mediastinoscopy. Mediastinoscopy is a surgical procedure to examine the inside of the upper chest between and in front of the lungs (mediastinum), which requires a general anaesthetic and a 2-3 day inpatient stay. The operation is expensive and has a low but not insignificant complication rate. Recently, two minimally invasive screening techniques have been described for sampling lymph nodes by accessing them via the gullet (endoscopic ultrasound guided fine needle aspiration or EUS-FNA) or via the windpipe and main lung passages (endobronchial ultrasound guided transbronchial needle aspiration or EBUS-TBNA). The advantage of these approaches is that they are normally performed under local anaesthetic and sedation as a day case procedure, are cheaper and have virtually no complications. To date there are no studies comparing these two techniques with mediastinoscopy. The aim of this study is to compare the accuracy of cancer staging, cost effectiveness and complications of EBUS/EUS and mediastinoscopy.

Who can participate?
Lung cancer patients who require a mediastinoscopy as part of their routine investigations

What does the study involve?
Participants are randomly allocated to undergo either mediastinoscopy or EBUS/EUS (followed by mediastinoscopy if negative). Biopsy samples from lymph nodes taken by the new techniques are compared with biopsies taken by the surgical technique.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Papworth Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2007 to November 2010

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Robert Rintoul
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https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-different-ways-of-checking-lymph-nodes-in-the-chest-for-non-small-cell-lung-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00432640

Protocol serial number
HTA 06/302/216; P01198

Study information

Scientific Title
A randomised, controlled trial of surgical staging with endobronchial and endoscopic ultrasound for assessment of the mediastinum in lung cancer

Acronym
ASTER

Study objectives
The hypothesis is that endobronchial/endoscopic staging is as accurate as surgical staging.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/06302216
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/51309/PRO-06-302-216.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Cambridge 1 Research Ethics Committee (REC) (UK), 29/05/2007
2. Ghent University Hospitals REC (Belgium)

Approval pending for centres in Denmark and Germany. These centres will not be recruiting patients before REC approval has been granted.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Non small cell lung cancer

Interventions
Patients will be randomised to have surgical mediastinal staging or staging via Endobronchial and Endoscopic Ultrasound (EBUS/EUS).

EBUS/EUS (the research specific intervention):
This takes place in the bronchoscopy suite as a day case procedure under light sedation. The EBUS/EUS probes are passed down the trachea and oesophagus, respectively, and sequentially. Lymph nodes which have been identified by Computed Tomography (CT) scan (routine practice procedure) are biopsied and sent to the histopathology laboratory for histological analysis. The results of the histology inform the staging result. The staging result determines whether or not a patient is suitable for surgical resection of their lung cancer.

Surgical staging:
The surgical staging is conducted under general anaesthetic. Lymph nodes which have been identified by CT are biopsied and processed as above.

The histology samples will be analysed as soon as they are obtained. In those patients whose staging confirms that they are suitable to proceed to surgical resection, the true negative/false negative status of the histology samples will confirmed. Surgical resection occurs within 14 days of the staging.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Sensitivity of Endobronchial and Endoscopic Ultrasound (EBUS/EUS)

Key secondary outcome(s))
1. Utility
2. Number of surgical procedures that can be avoided if EBUS/EUS is used

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Patients with a known diagnosis of non small cell lung cancer
2. Patients fit for bronchoscopy, endoscopy and surgical procedures

Male and female adult patients will be recruited - there is no upper age limit.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
241

Key exclusion criteria
1. Evidence of metastatic spread
2. Concurrent malignancy
3. Uncorrected coagulopathy
4. Inability to consent

Date of first enrolment
01/12/2007

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
United Kingdom

England

Belgium

Denmark

Germany

Study participating centre
Papworth Hospital NHS Foundation Trust
Cambridge
United Kingdom
CB23 8RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No
Other publications	health economics analysis	01/07/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes