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	[X] Prospectively registered [_] Protocol
Registration date 14/06/2007	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 26/10/2022	Condition category Cancer	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 robert.rintoul@papworth.nhs.uk

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00432640

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s)

Hospital

Study type(s) Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Sensitivity of Endobronchial and Endoscopic Ultrasound (EBUS/EUS)

Secondary outcome measures

Utility
 Number of surgical procedures that can be avoided if EBUS/EUS is used

Overall study start date

01/12/2007

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

Age group Adult

Sex Both

Target number of participants 142

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 Belgium

Denmark

England

Germany

United Kingdom

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

Sponsor information

Organisation Papworth Hospital NHS Foundation Trust (UK)

Sponsor details

Papworth Everard Cambridge England United Kingdom CB23 3RE +44 (0)1480 364451 alistair.grant@papworth.nhs.uk **Sponsor type** Hospital/treatment centre

Website http://www.papworthpeople.com/

ROR https://ror.org/01qbebb31

Funder(s)

Funder type Government

Funder Name Health Technology Assessment Programme

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

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan Not provided at time of registration

IPD sharing plan summary Not provided at time of registration

Study outputs Output type

Details

<u>Results article</u>	results	01/05/2012		Yes	No
Other publications	health economics analysis	01/07/2014		Yes	No
<u>Plain English results</u>			26/10/2022	No	Yes