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BOOST: A new pathway with BronchOscopic or Oesophageal ultrasound for lung cancer diagnosis and STaging

Submission date	Recruitment status	[_] Prospectively registered
27/03/2008	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
23/05/2008	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-endobronchial-ultrasound-or-endoscopic-ultrasound-to-diagnose-lung-cancer-and-see-how-far-it-has-spread

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00652769

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of endobronchial ultrasound or endoscopic ultrasound as a first test in the diagnosis and staging of lung cancer

Acronym
BOOST

Study objectives
EUS (endoscopic ultrasound) or EBUS (endobronchial ultrasound guided transbronchial needle aspirate) as a first test after computed tomography (CT) scan in the diagnosis and staging of lung cancer will result in a reduction in the time from first outpatient referral to treatment decision, a reduction in the total number of positron emission tomography (PET) scans, mediastinoscopies and futile thoracotomies, fewer outpatient attendances and a reduction in NHS healthcare costs.

As of 22/02/2011 the anticipated end date for this trial has been updated from 31/10/2010 to 01/10/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charing Cross Research Ethics Committee (REC) on behalf of the National Research Ethics Service REC on 08/02/2008 (ref: 07/H0711/127)

Study design
Open-label multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Lung cancer

Interventions
Control arm: bronchoscopy, CT guided lung biopsy, PET scan, mediastinoscopy
Active arm: endobronchial or endoscopic ultrasound (EUS or EBUS, respectively)

Follow-up is for one year for all participants.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time from first outpatient appointment to decision to treat.

Information for the endpoints will be collected prospectively as patients go through the diagnostic and staging process and case report forms (CRFs) will be updated weekly. The information will be obtained from multi-disciplinary team meetings (MDTs), patient notes and electronic patient records.

Secondary outcome measures
1. The health care costs of diagnosing and staging lung cancer
2. The number of tests and outpatient visits a patient requires to be diagnosed and staged with lung cancer
3. The proportion of lung cancer patients that are diagnosed and staged with a single test after CT scan
4. The time from first outpatient appointment to treatment
5. The number of futile thoracotomies

Information for the endpoints will be collected prospectively as patients go through the diagnostic and staging process and case report forms (CRFs) will be updated weekly. The information will be obtained from multi-disciplinary team meetings (MDTs), patient notes and electronic patient records.

Overall study start date
07/04/2008

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Aged greater than 18 years, either sex
2. Consecutive patients suspected of lung cancer on CT scan
3. Written informed consent
4. Able to tolerate fibre-optic bronchoscopy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
168

Total final enrolment
133

Key exclusion criteria
1. Evidence of severe or uncontrolled systemic disease that makes it undesirable for the patient to participate in the trial
2. Any disorder making reliable informed consent impossible
3. Patient unlikely to tolerate bronchoscopy
4. Patients with extra-thoracic disease, supraclavicular lymphadenopathy or pleural effusion

Date of first enrolment
07/04/2008

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Respiratory Research
London
United Kingdom
WC1W 6JF

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
235 Euston Road
London
England
United Kingdom
NW1 2BU

Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk/

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

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	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2015	10/09/2019	Yes	No
Plain English results			25/10/2022	No	Yes