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The impact of Positron Emission Tomography (PET) imaging in staging potentially surgically resectable non-small cell lung cancers: a prospective, multicentre randomised clinical trial

Submission date
05/11/2007

Recruitment status
No longer recruiting

Registration date
05/11/2007

Overall study status
Completed

Last Edited
13/07/2009

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00136890

Protocol serial number
MCT-78777

Study information

Scientific Title

Acronym
ELPET Trial

Study objectives
In patients with clinical stage I - IIIA Non-Small Cell Lung Cancer (NSCLC) who are potential candidates for surgery with curative intent, to determine whether preoperative whole body PET or PET-Computed Tomography (CT) in conjunction with cranial imaging identifies more precisely those patients with occult mediastinal or extrathoracic metastatic disease, thereby sparing them from undergoing stage-inappropriate therapies, when compared to conventional preoperative staging (CT liver/adrenals, total body bone scan, CT with contrast or Magnetic Resonance Imaging [MRI] with gadolinium of the brain).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of University Health Networks, Toronto, Ontario, Canada approved on the 12th March 2004 (ref: 04-0006-C).

Study design
Multicentre, two arm, randomised parallel trial exploring diagnostic strategy

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Stage I, II, IIIA Non-small Cell Lung Cancer

Interventions
PET Imaging versus Conventional Staging.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

The proportion of patients in the whole body PET/PET-CT plus brain CT/MRI arm versus the conventional staging arm who are correctly upstaged to stage IIIB or IV disease prior to planned treatment, thereby sparing patients from stage-inappropriate therapy (true positives), to be measured at any time during the first 2 years of the study.

Key secondary outcome(s))
To be measured any time during the first 2 years of the study:
1. The proportion of patients in each investigational arm that were erroneously understaged and were thereby subject to potentially stage-inappropriate therapy (false negatives), either because they were eventually shown to have pathologic stage III (A or B) disease at mediastinoscopy prior to planned thoracotomy or on lymph node sampling at thoracotomy, or because they developed local recurrence or distant metastases within two years of thoracotomy (pathologic stage IV)
2. For each investigational arm, the overall survival in patients with Stage I-IIIA NSCLC who undergo surgery with curative intent
3. The prognostic ability of the PET Standard Uptake Value (SUV) to predict overall survival in patients with clinical stage I-IIIA NSCLC
4. The sensitivity and specificity of PET/PET-CT in the staging of the mediastinum, when compared to lymph node sampling at thoracotomy
5. The cost-effectiveness of staging with PET versus conventional staging

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Histological or cytological proof of NSCLC
2. Stage I, II, or IIIA NSCLC based upon clinical staging
3. The primary lesion appears technically appropriate for surgical resection, based on information from the Chest X-Ray (CXR) and CT thorax
4. Male or female NSCLC patients, 18 years and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Poor pulmonary function precluding radical surgery (inadequate pulmonary reserve for radical surgery) with predicted post-resection Forced Exipiratory Volume in One second (FEV1) less than 0.8 l or less than 40% predicted, and Diffusing capacity of the Lung for Carbon Monoxide (DLCO) less than 40 % predicted
2. Poor performance status (Eastern Cooperative Oncology Group [ECOG] grade 3 - 4)
3. Significant concurrent medical problems (e.g. uncontrolled diabetes, active cardiac problems, significant chronic obstructive pulmonary disease) making the patient unfit for surgery
4. Pregnant or lactating females
5. Unable to lie supine for imaging with PET
6. Patients with previously treated cancer other than nonmelanotic skin cancer or carcinoma in situ of the cervix, unless disease-free for 5 years or greater
7. Patients who, at the time of the initial evaluation, have already undergone a whole body PET /PET-CT, CT brain, MRI brain, total body bone scan or mediastinoscopy within 8 weeks prior to randomisation will be excluded. However, patients who have had a CT scan of the thorax with abdomen are not excluded
8. Failure to provide informed consent

Date of first enrolment
01/07/2004

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Canada

Study participating centre
Ontario Clinical Oncology Group (OCOG)
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Sponsor information

Organisation
McMaster University (Canada)

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-78777)

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	18/08/2009		Yes	No