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Can Dynamic Contrast Enhanced Computed Tomography (DCE-CT) scans aid in the diagnosis of early stage lung cancer and are they cost effective?

Submission date 28/05/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2012	**Overall study status** Completed	
Last Edited 16/03/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-2-different-ways-to-diagnose-lung-cancer-sputnik

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02013063

Protocol serial number
HTA: 09/22/117

Study information

Scientific Title
Accuracy and cost-Effectiveness of Dynamic Contrast Enhanced Computed Tomography in the characterisation of solitary pulmonary nodules

Acronym
SPutNIk

Study objectives
A DCE-CT scan, either alone or in conjunction with fluorodeoxyglucose positron emission tomography (FDG-PET)/CT scan, can aid in the early diagnosis of lung cancer in patients where a single pulmonary nodule has been detected by conventional CT scan and that this is more cost effective than monitoring with conventional CT scans for up to two years.

More details can be found at http://www.hta.ac.uk/project/2790.asp

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diagnosis of early stage lung cancer in a population that have a single pulmonary nodule detected by conventional CT scan

Interventions
This is a diagnostic study involving the addition of a single DCE-CT scan, performed on the same day or within 2 weeks of a FDG-PET/CT scan which is standard NHS care for patients presenting with an SPN on conventional CT scan.

Patients will be followed up for a period of two years or until diagnosis under standard NHS care.

Outcomes of early stage lung cancer or not will be compared to scan data from DCE-CT scans ± FDG-PET/CT scans to assess accuracy of diagnosis and cost effectiveness of DCE-CT scans.

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
1. Diagnostic test characteristics of sensitivity, specificity and accuracy for both FDG-PET/CT and DCE-CT scans in relation to a subsequent clinical diagnosis of lung cancer.
2. Economic model will include accuracy, estimated life expectancy, and quality adjusted life years (QALYs)
3. Costs will be estimated from an NHS perspective. Incremental cost-effectiveness ratios will compare management strategies with DCE-CT to strategies without DCE-CT.

Key secondary outcome(s))
1. Diagnostic test characteristics for FDG-PET/CT with incorporation of CT appearances and combined DCE-CT/FDG-PET scans.
2. Incidence of incidental extra-thoracic findings on FDG-PET/CT and subsequent investigations and costs will also be determined.

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. A soft tissue solitary dominant pulmonary nodule of ≥ 8mm and ≤ 30mm on axial plane, measured on lung window using conventional CT scan with no other ancillary evidence strongly indicative of malignancy (e.g. distant metastases) or unequivocal local invasion.
2. 18 years of age or over at time of providing consent
3. Able and willing to consent to study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
355

Key exclusion criteria
1. Pregnancy
2. History of malignancy within the past 2 years
3. Confirmed aetiology of the nodule

4. Biopsy of nodule prior to DCE-CT scan
5. Contra-indication to potential radiotherapy or surgery
6. Contra indication to scans (assessed by local procedures)

Date of first enrolment
01/09/2012

Date of final enrolment
16/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mailpoint 805
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) (ref: 09/22/117)

Results and Publications

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	01/11/2020	03/11/2020	Yes	No
Results article	Health Technology Assessment programme results publication	01/03/2022	16/03/2022	Yes	No
Protocol article	protocol	14/10/2016	17/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes