ISRCTN30784948 https://doi.org/10.1186/ISRCTN30784948

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

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

**Plain English Summary**
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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT02013063

### Secondary identifying numbers
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 hypothesis
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

### Secondary study design
Other

### 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

### Condition
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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
01/09/2012

### Overall study end date
30/04/2019

## Eligibility

### Participant 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

### Age group
Adult

**Lower age limit**
18 Years

**Sex**
Both

**Target number of participants**
375

**Total final enrolment**
355

**Participant 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)

**Recruitment start date**
01/09/2012

**Recruitment end date**
16/12/2016

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Mailpoint 805**
Southampton
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SO16 6YD

# Sponsor information

**Organisation**
University Hospital Southampton NHS Foundation Trust (UK)

**Sponsor details**

Research and Development
SGH - Level E
Laboratory and Pathology Block
SCBR - MP 138
Southampton General Hospital
Southampton
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### Sponsor type
Hospital/treatment centre

### 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

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