# A randomised controlled trial of surveillance for the early detection of lung cancer in an at risk group

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered			
01/02/2007		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
13/03/2007	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
23/09/2020	Cancer				

### Plain English summary of protocol

http://www.cancerhelp.org.uk/trials/a-trial-to-find-out-if-screening-can-pick-up-lung-cancer-at-an-early-stage-in-a-high-risk-group-of-people-the-lungsearch-study

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

NCT00512746

# Secondary identifying numbers

BRD/06/107

# Study information

#### Scientific Title

A randomised controlled trial of surveillance for the early detection of lung cancer in an at risk group

#### Acronym

Lung-SEARCH

#### Study objectives

The trial will test the hypothesis that annual surveillance of chronic obstructive pulmonary disease (COPD) patients who are long-term smokers with abnormal sputum cytology and/or cytometry using fluorescence bronchoscopy and low dose spiral computed tomography (CT) detects a large proportion of lung cancer incidence at early stages when curative treatment is feasible.

Please note that as of 03/10/2008 this record has been updated. Any changes to the trial information can be found in the relevant field under the above update date.

On 17/02/2011 the target number of participants was changed from 1300 to 1700.

#### Ethics approval required

Old ethics approval format

## Ethics approval(s)

South West Research Ethics Committee, 11/04/2007, ref: 07/MRE06/16

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Screening

### Participant information sheet

## Health condition(s) or problem(s) studied

Lung cancer

#### **Interventions**

Amended as of 03/10/2008:

Point one in the surveillance arm (a baseline blood sample will be taken) has now been removed from the interventions section. All other information remains the same.

Initial information at time of registration:

In the surveillance arm:

- 1. A baseline blood sample will be taken
- 2. A sputum sample will be collected for cytology and cytometry:
- 2.1. Normal sputum = sputum without metaplastic cells, only containing alveolar macrophages. If the sputum sample is normal the subject will be asked to provide sputum annually.
- 2.2. Abnormal sputum = low-grade (LSIL) and high-grade lesion (HSIL) squamous intraepithelial lesions. If the sputum sample is abnormal the subject will have an annual CT scan followed by a fluorescence bronchoscopy. The frequency of bronchoscopy is dependent upon the histology results.

#### In the control arm:

Patients recruited into the control arm will be managed according to the usual practice of their hospital or general practice for their COPD treatment. They will have no particular investigations except those that may arise due to a change in their clinical condition. However, those patients not diagnosed with lung cancer during the course of the study, will be offered an exit chest x-ray after 5 years.

#### **Intervention Type**

Other

#### Phase

Phase III

#### Primary outcome measure

The primary endpoint is the proportion of lung cancers that are diagnosed at stage I or II.

#### Secondary outcome measures

- 1. Uptake of screening (the proportion of patients in the surveillance arm who attend each year, among those invited to attend). This can be further divided into those who decline auto-FB, CT scan or yearly sputum.
- 2. The proportion of patients in the surveillance arm who have abnormal sputum cytology
- 3. The proportion of patients in the surveillance arm who have abnormal sputum cytometry
- 4. Death from lung cancer
- 5. Proportion of failed sputum samples, i.e. where it is not possible to obtain adequate sputum samples
- 6. Prevalence of pre-invasive disease in patients with abnormal cytometry in the active arm
- 7. Numbers of patients with pre-invasive lesions developing lung cancer locally and at remote sites within the lung in the active arm

#### Overall study start date

01/05/2007

#### Completion date

01/05/2014

# **Eligibility**

#### Key inclusion criteria

Amended as of 03/10/2008:

Point two of the inclusion criteria has been amended as follows:

2. Ex-smokers who have quit within 8 years with a greater than or equal to 20 pack-years smoking history and/or 20-year duration of smoking

Initial information at time of registration:

- 1. Current smokers: greater than or equal to 20 pack-years smoking history and/or 20-year duration of smoking
- 2. Ex-smokers who have quit within 5 years with a greater than or equal to 20 pack-years smoking history and/or 20-year duration of smoking
- 3. No upper age limit but life expectancy must be at least 5 years
- 4. No history of malignant disease during the previous 5 years except non-melanomatous skin cancers
- 5. No other serious co-morbidity
- 6. Written informed consent
- 7. Mild to moderate COPD as defined by the Global Initiative on Obstructive Lung Disease (GOLD) criteria
- 8. Mild:
- 8.1. Forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) less than 70
- 8.2. FEV1 greater than or equal to 80% predicted
- 9. Moderate:
- 9.1. FEV1/FVC less than 70%
- 9.2. FEV1 50-80% predicted

(Spirometric values will be taken post bronchodilator according to the recommendations in the GOLD criteria)

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

## Target number of participants

1700

#### Total final enrolment

1568

#### Key exclusion criteria

- 1. Inadequate lung function (FEV1 less than 50% predicted after bronchodilator)
- 2. History of malignant disease during the previous 5 years except non melanomatous skin cancers
- 3. Evidence of severe or uncontrolled systemic diseases that, in the view of the investigator, makes it undesirable for the patient to participate in the trial

- 4. Any disorder making reliable informed consent impossible
- 5. Patient unlikely to co-operate with a 5 year follow up

#### Date of first enrolment

24/08/2007

#### Date of final enrolment

01/04/2011

## Locations

## Countries of recruitment

England

**United Kingdom** 

## Study participating centre University College London Hospitals NHS Trust

London United Kingdom WC1E 5DB

# Sponsor information

#### Organisation

University College London (UK)

#### Sponsor details

University College London Rowland Hill Street London England United Kingdom NW3 2PF

#### Sponsor type

University/education

#### **ROR**

https://ror.org/02jx3x895

# Funder(s)

### Funder type

Charity

#### Funder Name

Cancer Research UK (CRUK) (UK) (ref: C5784/A7743)

### Alternative Name(s)

CR UK, Cancer Research UK - London, CRUK

#### **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### 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

# 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	01/01 /2016		Yes	No
Abstract results	results presented at the European Respiratory Society Annual Congress	01/06 /2012	15/04 /2019	No	No
Results article	qualitative results from interviews of a sample of people accepting and declining participation	01/05 /2012	15/04 /2019	Yes	No
Plain English results			23/09 /2020	No	Yes