

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

Submission date 01/02/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/09/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

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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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00512746

Protocol serial number

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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

University College London Hospitals NHS Trust
London
United Kingdom
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Sponsor information

Organisation

University College London (UK)

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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No
Results article	qualitative results from interviews of a sample of people accepting and declining participation	01/05/2012	15/04/2019	Yes	No
Abstract results	results presented at the European Respiratory Society Annual Congress	01/06/2012	15/04/2019	No	No
Plain English results			23/09/2020	No	Yes