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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2007	**Overall study status** Completed	
Last Edited 23/09/2020	**Condition category** 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

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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
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Sponsor information

Organisation
University College London (UK)

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University College London
Rowland Hill Street
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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