

Screening for lung cancer by chest radiography

Submission date 12/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/06/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Using chest x-rays to screen for lung cancer was suggested in the 1990s by four Japanese studies to reduce death rates (mortality). However, the results of have yet to be confirmed in western countries, and none of several other studies showed a mortality reduction after chest x-ray screening. Studies performed in the 1970s failed to answer the question of the effectiveness of x-ray screening; however, the possibility was recognized that a small but important benefit from annual x-rays could have been missed. The effectiveness of screening for lung cancer on a population level therefore remains controversial. The aim of this study is to assess whether x-ray screening decreases lung cancer mortality at a population level.

Who can participate?

Current smokers or ex-smokers, aged 45 to 75

What does the study involve?

Screening consists of a chest x-ray at the start of the study and annual repeat chest x-rays for 4 years, with usual care follow-up. The lung cancer death rates are compared with the results from a group who receive usual care without screening.

What are the possible benefits and risks in participating?

The possible benefits include an increased chance of surviving lung cancer. The possible risks include false-positive test results, futile diagnosis of a benign (non-cancer) lesion, complicated invasive diagnosis of a benign lesion, and anxiety from the detection of an indeterminate lesion.

Where is the study run from?

University of Insubria (Italy)

When is the study starting and how long is it expected to run for?

July 1997 to December 2017.

Who is funding the study?

University of Insubria (Italy)

Who is the main contact?
Prof. Lorenzo Dominioni
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Screening for lung cancer by chest radiography: a non-randomised cohort study

Study objectives

1. To ascertain whether chest radiography screening in smokers and ex-smokers at community level decreases lung cancer specific mortality
2. To evaluate the lung cancer detection results and the long-term survival in radiographic screening participants as well as in non-participants of the screening invited population based cohort
3. To estimate cost-effectiveness of radiographic screening for lung cancer and to help policy decision making

Ethics approval required
Old ethics approval format

Ethics approval(s)

Varese Hospital and Health District Ethics Committee, 20/05/1997

Study design

Non-randomized screening comparison cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Lung cancer

Interventions

1. Baseline CXR screening and annual repeat screen for 4 years, in addition to usual care
2. Smoking cessation advice

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Lung cancer specific mortality (reduction)

Secondary outcome measures

1. Lung cancer detection results:
 - 1.1. Lung cancer stage distribution
 - 1.2. Histological subtype distribution
 - 1.3. Resectability
2. Overall survival and lung-cancer specific survival
3. Cost-effectiveness

Overall study start date

01/07/1997

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Subjects of both genders
2. 45-75 years of age
3. Cigarette smoking history of >10 pack-years (current smoker or ex-smoker for less than 10 years)
4. Resident in Italy
5. Do not have symptoms of lung cancer:
 - 5.1. Bloody or worsening cough
 - 5.2. Hoarseness
 - 5.3. Unexplained weight loss
6. Not diagnosed with or suspected of having lung cancer

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

7000

Key exclusion criteria

1. Moderate or poor health
2. Unfit for possible thoracotomy

Date of first enrolment

01/07/1997

Date of final enrolment

01/12/2013

Locations

Countries of recruitment

Italy

Study participating centre

University of Insubria

Varese

Italy

21100

Sponsor information

Organisation

University of Insubria (Italy)

Sponsor details

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Sponsor type

University/education

Website

<http://www.uninsubria.it/uninsubria/home.html>

ROR

<https://ror.org/00s409261>

Funder(s)

Funder type

University/education

Funder Name

Università degli Studi dell'Insubria

Alternative Name(s)

University of Insubria

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Funder Name

Associazione PREDICA Onlus (Italy)

Funder Name

Lions Clubs District 108 Ib-1 annual grants (Italy)

Funder Name

Associazione AMARE, Como (Italy)

Funder Name

Associazione P. Giancola per la Ricerca sul Cancro, Como (Italy)

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	preliminary results	01/12/2000		Yes	No
Other publications	self-selection effects	01/04/2010		Yes	No