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Spiral computed tomography scanning for the early detection of lung cancer

Submission date	Recruitment status	[X] Prospectively registered
29/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/07/2021	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Spiral computed tomography scanning for the early detection of lung cancer

Acronym
LUSI

Study objectives
Lung cancer sreening with Multislice Spiral Computed Tomography (MSCT) reduces the mortality from lung cancer by at least 20%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee: Alte Glockengiesserei 11/1, 69115 Heidelberg (Germany), approved on 7 March 2007 (ref: 073/2001)

Study design
Randomized controlled trial with an MSCT screening arm and an usual care control arm.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Lung cancer

Interventions
Intervention arm:
1. MSCT-scanning for the early detection of lung cancer immediately at time of randomisation and 4 times annually
2. Further assessment of suspicious nodules according to an internationally agreed algorithm
3. Counselling aimed at smoking cessation at time of randomisation

Control arm: Counselling aimed at smoking cessation at time of randomisation.

Both arms will receive annual follow-up by mailed questionnaires for assessment of Disease outcome for further 5 years after the 5 screening rounds of the intervention group. At time of

randomization 20 ml blood sample will be taken in both intervention and control arms for concomitant biomarker research.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Mortality from lung cancer at 5 and 10 years.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/2007

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Age 50-69
2. Smoking history of at least 40 pack-years
3. If under the age of 60, current smokers or ceased smoking within the last five years
4. Able to complete a self-administered epidemiology questionnaire providing details on smoking history, family history of lung and other cancers (if any), occupational history and previous illnesses
5. Agree to be randomised to screening with annual low dose spiral CT plus smoking cessation counseling or only smoking cessation counseling
6. Have signed an informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4000

Total final enrolment
4052

Key exclusion criteria

1. History of lung cancer or other malignancy (except basal cell carcinoma)
2. History of a disease that would preclude surgical as well as medical treatment of lung cancer
3. Other serious illness that would reduce life expectancy to less than 10 years

Date of first enrolment
01/08/2007

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Germany

Study participating centre
German cancer research center
Heidelberg
Germany
69120

Sponsor information

Organisation
German Cancer Research Centre (Deutsches Krebsforschungszentrum)

Sponsor details
c/o Prof Otmar Wiestler
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Sponsor type
Research organisation

ROR
https://ror.org/04cdgtt98

Funder(s)

Funder type
Not defined

Funder Name
German Research Foundation (ref: BE2486/2-1)

Funder Name
Dietmar Hopp Foundation (Dietmar-Hopp-Stiftung) (ref: DL-26.1.07) (Germany)

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		01/03/2021	27/07/2021	Yes	No