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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

**Protocol serial number**
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

## Study type(s)
Diagnostic

## 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(s)
Mortality from lung cancer at 5 and 10 years.

## Key secondary outcome(s))
No secondary outcome measures

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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)

**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

**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 |