# A randomized clinical trial of surgery or radiosurgery (stereotactic radiotherapy) in patients with stage IA non-small cell lung cancer who are fit to undergo primary resection

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To compare the outcomes of stereotactic radiotherapy (experimental arm) with that following primary surgery (standard arm) in a prospective phase III trial.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory and mediastinal neoplasms malignant and unspecified |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32289

**Source**
ToetsingOnline

**Brief title**
Randomized trial of surgery or radiosurgery in stage IA lung cancer

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Lower respiratory tract disorders (excl obstruction and infection)
- Respiratory tract therapeutic procedures

**Synonym**
stage IA NSCLC; operable early-stage lung cancer

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** medically operable, primary surgery, stage IA non-small cell lung cancer, stereotactic radiotherapy

## Outcome measures

### Primary outcome

To compare local and regional control, quality of life and treatment costs at

2- and 5-years, in patients with stage IA NSCLC who are randomized to either

surgery or radiosurgery.

### Secondary outcome

Overall survival, pulmonary function tests, quality adjusted life years

(QALYs), total costs (both direct and indirect).

# Study description

### Background summary

Stage I non-small cell lung cancer only makes up 20% of the nearly 9000 patients diagnosed to have lung cancer in the Netherlands. Despite a complete surgical resection, tumor recurrences are seen in nearly 35% of patients, and the 5-year survival is less than 70%. More effective, and less toxic, treatments are needed. Stereotactic radiotherapy is a well-tolerated outpatient procedure which can achieve local control in more than 90% of patients with medically-inoperable stage IA NSCLC.

### Study objective

To compare the outcomes of stereotactic radiotherapy (experimental arm) with that following primary surgery (standard arm) in a prospective phase III trial.

### Study design

A prospective phase III trial.

### Intervention

Primary stereotactic radiatherapy will be the experimental arm, and patients will receive a dose of 60Gy in either 3 or 5 fractions.

### Study burden and risks

The commonest complications described after stereotactic radiotherapy (experimental arm) are chest pain and radiation-induced lung inflammation. However, this has been described in less than 6% of treated patients and studies of quality of life after stereotactic radiotherapy show less impairment than after surgery (standard arm). Patients undergoing stereotactic radiotherapy are at greater risk of tumor recurrences in hilar and mediastinal nodes, but these are amenable to salvage treatment options with surgery and/or chemo-radiotherapy.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Age * 18 years;Patients with a diagnosis of stage IA non-cell lung cancer diagnosed in accordance with Dutch CBO guidelines. When no pathological diagnosis is available, a patient with a new or growing pulmonary lesion with radiological features consistent with malignancy AND a lesion showing uptake on a FDG-PET scan will be eligible. ;No evidence of regional or distant metastases on a standardized FDG-PET scan within 6 weeks of any protocol treatment .;Medial extension of tumours should be least 2 cm away from main and lobar bronchi, and also minimum of 1.5 cm from large peripheral blood vessels such as the aorta and main pulmonary artery. Lesions of at least 2 cm from the mediastinal pleura will be eligible if the responsible radiation oncologist judges that the specified normal tissue tolerance doses specified in the protocol will not be exceeded.;Patients should be fit to undergo both surgery and SRT. ;Patients who are judged by a multi-disciplinary team to have 2 primary lung tumors (on the basis of clinical, radiological, FDG-PET and/or cyto-pathology findings) are eligible for randomization provided that both surgery and SRT can be performed in accordance with protocol requirements.;Patient should be fit to undergo a complete surgical resection of the lesion in accordance with Dutch CBO guidelines [2004] ;Performance score of ECOG * 2 before any treatment.;Able to comply with post-treatment follow-up

## Exclusion criteria

Prior chemotherapy or radiotherapy for the present diagnosis of NSCLC. ;History of any active malignancy (other than NSCLC) unless treated more than 3 years with curative intent and no recurrence, with the exception of non-melanoma skin cancers or in-situ cervical cancers.;Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, severe cardiac arrhythmia requiring medication, hepatic, renal or metabolic disease).;Concomitant treatment with any other experimental drug under investigation.

# Study design

## Design

Study phase: 3

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2008 |
| Enrollment: | 960 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 29-07-2008 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
| --- | --- |
| ClinicalTrials.gov | NCT00687986 |
| CCMO | NL23511.029.08 |