# Video-assisted thoracic surgery versus open lobectomy for lung cancer: a randomized prospective trial

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To compare quality of life, cost-effectivenessand number of dissected mediastinal lymph node as a derivative oncologic outcome between open- and VATS lobectomy.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Respiratory tract neoplasms |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37381

**Source**
ToetsingOnline

**Brief title**
VATS versus open lobectomy

### Condition

- Respiratory tract neoplasms

**Synonym**
lung cancer, pulmonary carcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** ZonMw subsidie aangevraagd

## Intervention

**Keyword:** lobectomy, thoracoscopic, video-assisted

## Outcome measures

### Primary outcome

Primary endpoints are postoperative quality of life, number of dissected mediastinal lymph nodes for oncologic staging, hospital length of stay and overall costs.

### Secondary outcome

Secondary endpoints include procedural complication rates, pulmonary function and survival.

# Study description

### Background summary

Surgical lobectomy is the treatment of choice for patients with early stage lung cancer. In some centres, video-assisted thoracic surgery (VATS) lobectomy is preferred, where several other centres hold on to the conventional open lobectomy via a thoracotomy. Although several studies have demonstrated fewer postoperative complications and shorter hospital length of stay for the VATS procedure, others reported concerns regarding oncologic staging. Convincing randomized evidence from the literature is lacking. The aim of this randomized multicentre study is to compare quality of life, oncologic endpoints and cost-effectiveness between VATS- and open (thoracotomy) lobectomy.

### Study objective

To compare quality of life, cost-effectivenessand number of dissected mediastinal lymph node as a derivative oncologic outcome between open- and VATS lobectomy.

### Study design

A prospective multi-centre randomized trial.

### Intervention

One group is assigned to the open procedure: posterolateral thoracotomy for lobectomy with mediastinal lymph node dissection. The other group is assigned to the VATS procedure: thoracoscopic minimally invasive lobectomy with thoracoscopic mediastinal lymph node dissection.

### Study burden and risks

Centres participating in this study currently perform the open- and VATS lobectomy in daily clinical practice. Either intervention therefore does not introduce an extra risk for the patient. Assessment of quality of life and pain scores carry an extra burden for the patient, but are necessary elements to define the difference between open- and VATS lobectomy. There is no direct benefit for patients to participate.

## Contacts

**Public**
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10, postbus 9101
6500 HB Nijmegen
NL
**Scientific**
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10, postbus 9101
6500 HB Nijmegen
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

Patients selected by multidisciplinary oncologic team to undergo lobectomy
Non-small cell lung carcinoma, pathologically confirmed or strong suspicion based on imaging.
T1 or T2a (<= 5 cm) on computer tomography (CT).
Primary aim is lobectomy.
Tumor is not in close relation to central structures (main bronchus, pulmonary artery or pulmonary veins) and is surrounded by lung parenchym (based on CT).
Clinically staged N0 or N1 (lymfnodes), M0 (no distant metastasis) after clinical staging according to the current Dutch guideline (may 2011).

### Exclusion criteria

T2b, T3 or T4 tumor (7th guideline TNM classification NSCLC).
Mediastinal lymph node metastasis (N2, N3).
Distant metastasis (M1).
Previous thoracic surgery on same side.
Pneumonectomy as primary aim.

## Study design

### Design

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|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 23-05-2013 |
| Enrollment: | 160 |

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| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 24-07-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 13-09-2013 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 03-04-2014 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 29-07-2014 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 |
|---|---|
| CCMO | NL40542.091.12 |