# Complete endosonographic intrathoracic nodal staging of lung cancer patients in whom SABR is considered.

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Complete endosonographic (combined endobronchial and esophageal) staging of hilar and mediastinal lymph nodes in patients with (suspected) non-small cell lung cancer (NSCLC) will result in change of loco-regional nodal status in 20% of patients, in...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory tract neoplasms |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON44668

**Source**
ToetsingOnline

**Brief title**
STAGE

### Condition

- Respiratory tract neoplasms

**Synonym**
lung cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** EBUS and EUS, lung cancer, Nodal staging, SABR

## Outcome measures

### Primary outcome

Change of loco-regional nodal status (N0-N3) after complete endosonographic staging (EBUS+EUS-B) of the hilus and mediastinum versus initial PET-CT based loco-regional nodal status. The primary hypothesis will be tested in patients with (suspected) non-small cell lung cancer (NSCLC) when SABR with curative intent is considered.

### Secondary outcome

Radiotherapy plan comparisons for the pre EUS-EBUS staging versus post-staging target volumes

# Study description

### Background summary

Accurate staging of lung cancer is important because it directs treatment and determines prognosis. The development of SABR (high-precision radiotherapy) has revolutionized radiation therapy for early stage lung cancer and results demonstrate similar outcomes in comparison to surgical resection of the lung tumor. Staging work-up program for patients with potentially resectable NSCLC includes at least CT scans of the chest and integrated PET-CT scans, and when indicated, (minimally) invasive mediastinal staging. However, patients who are treated with SABR do not routinely undergo the same nodal staging work-up as do surgical candidates. As both surgery and SABR appear to achieve comparable rates of local and regional tumor control, it appears only logical to perform a similar staging work-up in all patients with early stage lung cancer who will be treated with either of the two curative local modalities. In the past, a lack of invasive nodal sampling before SABR was considered acceptable as invasive surgical staging (mediastinoscopy) was widely considered the preferred procedure. However, with minimally invasive and safe endosonography procedures that are currently available, improved pre-treatment staging has become

possible for patient groups who are eligible for SABR, despite the presence of a high rate of comorbidities.

### Study objective

Complete endosonographic (combined endobronchial and esophageal) staging of hilar and mediastinal lymph nodes in patients with (suspected) non-small cell lung cancer (NSCLC) will result in change of loco-regional nodal status in 20% of patients, in comparison to staging by PET-CT alone.

### Study design

Prospective, non-randomised diagnostic study. Setting: Multicentre (university and general hospitals)

### Study burden and risks

The burden and risks associated with participation are considered low. Patients who will be approached for study participation already have an indication for mediastinal tissue sampling in accordance with the current lung cancer staging guidelines. SABR for lung cancer is only considered appropriate when no hilar or mediastinal nodal metastases are present. We expect that in one out of five patients, intrathoracic nodal stage will change based on endosonography outcomes and therefore influence the therapeutic strategy

## Contacts

**Public**
Academisch Medisch Centrum

meibergdreef 9
amsterdam 1105 AZ
NL
**Scientific**
Academisch Medisch Centrum

meibergdreef 9
amsterdam 1105 AZ
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

(suspected) non small cell lung cancer
absence of distant metastases
SABR is contemplated

### Exclusion criteria

bulky nodal disease based on PET-CT
contra-indication for endosonography

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-11-2013 |
| Enrollment: | 102 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 28-10-2013 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 04-02-2014 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 02-09-2014 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 17-04-2015 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-04-2015 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-06-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 18-10-2016 |
| Application type: | Amendment |
| 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 |
| --- | --- |
| CCMO | NL46486.018.13 |