Complete endosonographic staging of lung cancer: a systematic single scope approach.

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Complete endosonographic (combined endobronchial and esophageal) staging using a single EBUS scope improves locoregional staging (N2, N3, T4) versus EBUS (endobronchial) staging alone.

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

Summary

ID

NL-OMON39836

Source
ToetsingOnline

Brief title
SCORE
Sinlge scope complete staging of lung cancer with endosonography.

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, EUS, Lung cancer, Mediastinal staging

Outcome measures

Primary outcome

The main study parameter is the sensitivity for loco regional disease (N2, N3, T4 disease) of complete endosonographic staging (by EBUS-TBNA and EUS-B-FNA) in comparison to EBUS staging alone.

Secondary outcome

1. Sensitivity for locally advanced disease (N2-3 metastases, T4) of systematic assessment and sampling of mediastinal lymph nodes in comparison to PET-CT directed assessment of the mediastinum (ie targeted approach).

2. The assessment of the left adrenal gland by EUS-B is feasible.

Study description

Background summary

Lung cancer is the most commonly diagnosed cancer worldwide and is the most frequent cause of cancer death. Accurate staging is important because it directs treatment and prognosis. Mediastinal staging can be done by both EBUS-TBNA and EUS-FNA. These two techniques have a complementary diagnostic range and the combined procedure is suited for assessment of almost the entire mediastinum. In practice endoscopists often perform only an EBUS or EUS when mediastinal staging is indicated instead of the combination. It is feasible to perform transoesophageal needle aspiration using an EBUS scope (EUS-B-FNA) and complete endosonographic staging of the mediastinum can also be performed using one scope. When mediastinal staging is indicated, mostly only one or two, by imaging suspected lymph node stations, are sampled (ie. targeted approach). This approach can underestimate the N-stage because the accuracy of PET-CT for diagnosing mediastinal disease is not optimal.

Study objective

Complete endosonographic (combined endobronchial and esophageal) staging using a single EBUS scope improves locoregional staging (N2, N3, T4) versus EBUS (endobronchial) staging alone.

Study design

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

Study burden and risks

The burden and risks associated with participation are considered low. Patients that will be approached for study participation have an indication for an endosonographic investigation. When they take part in this study the mediastinal staging procedure will be performed more extensively by combining an EBUS and EUS-B with routine sampling of at least three nodal stations.

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

lung cancer
indication for mediastinal staging
resectable lung tumor
patient is operable

Exclusion criteria

distant metastases of lung cancer
mediastinal lymph nodes not within reach of EBUS
former lung cancer treatment

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2013
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2013
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	NL42787.018.13