Endobronchial ultrasound in diagnosing and staging of Lung cancer22 G TBNB vs 22 G TBNA needles; a randomized controlled trial: EBUS Acquire™ Needle Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20056

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Lungcancer and mediastinal staging

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Boston Scientific

Intervention

Outcome measures

Primary outcome

1. The suitability rate for the assessment of PD-L1 expression with the EBUS / EUS-B 22 G TBNB novel Boston Acquire^{tm} needle vs 22 G TBNA Boston Scientific BSC standard needle on mediastinal/hilar nodal or tumor aspirates in patients with a final diagnosis of lung cancer.

Secondary outcome

- Cumulative length tissue core
- Suitability for molecular analysis/next-generation sequencing in patients with a final diagnosis of lung cancer
- Sample adequacy (defined as the presence of lymphocytes or atypical cells or other pathognomic characteristics (e.g. granulomas))
- Sample quality using the Mair's objective scoring system
- Sample bloodiness
- Diagnostic sensitivity for mediastinal/hilar nodal staging (defined as the proportion of patients that have N2/N3 disease diagnosed by EBUS/EUS-B, relative to the total number of patients with a final diagnosis of N2/N3 disease as determined by the reference standard)
- Diagnostic sensitivity for malignancy (defined as the proportion of patients that have malignancy diagnosed by EBUS/EUS-B, relative to the total number of patients with a final diagnosis of malignancy as determined by the reference standard)
- Yield for diagnosing malignancy in the subgroup of patients with a centrally located lung tumor (defined as the proportion of patients that have malignancy diagnosed by EBUS/EUS-B, relative to the total number of patients with a final diagnosis of malignancy)
- Complication rate
- Procedure duration
- Endoscopists satisfaction of needle use

Study description

Background summary

Patients with (suspected) lung cancer and an indication for mediastinal/hilar nodal or lung tumor sampling by EBUS-TBNA and /or EUS-B FNA according to current guidelines. Indications for mediastinal staging are: suspicion of mediastinal or hilar lymph node metastases based either on size (short axis > 10mm on CT) or increased FDG uptake; centrally located primary tumor, FDG-negative tumor). Centrally located lung tumors adjacent to the major airways or esophagus can be sampled by EBUS/EUS-B.

In this randomised study we will compare the novel Acquire^{tm} needle 22 G TBNB vs 22 G TBNA standard Boston Scientific needles for the diagnosis and staging of lung cancer.

Hypothesis: EBUS/EUS-B sampling of mediastinal/hilar lymph nodes and/or primary lung tumors with the Acquire^{tm} 22G TBNB needle has a higher suitability rate for the assessment of PD-L1 expression in comparison to the regular 22G TBNA needle in patients with lung cancer

Study objective

EBUS/EUS-B sampling of mediastinal/hilar lymph nodes and/or primary lung tumors with the Acquire^{tm} 22G TBNB needle has a higher suitability rate for the assessment of PD-L1 expression in comparison to the regular 22G TBNA needle in patients with lung cancer

Study design

-

Intervention

We will compare the novel Acquire^{tm} needle 22 G TBNB vs 22 G TBNA standard Boston Scientific needles for the diagnosis and staging of lung cancer

Contacts

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Eligibility criteria

Inclusion criteria

- (suspected) NSCLC/SCLC
- Indication for mediastinal/hilar nodal or lung tumor tissue sampling
- Suspected mediastinal/hilar lymph nodes or lung tumor within reach of EBUS/ EUS-B
- 18 years or older
- Provision of a written consent

Exclusion criteria

- Mediastinal re-staging after neo-adjuvant treatment
- Contra-indication for EBUS or EUS/B
- Not correctable coagulation disorder
- Pregnancy
- Inability to consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-09-2019
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data available upon reasonable request

Ethics review

Positive opinion

Date:	15-04-2019
Application type:	First submission

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
NTR-new	NL7701
Other	METC AMC : nl68824

Study results