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

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To determine if EBUS / EUS-B guided nodal/lung tumor sampling with 22 Gauge (G) TBNB (Acquire**) needles results in improved tissue core sample acquisition in comparison to standard 22 G TBNA needles for the diagnosis and staging of lung cancer.

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

Summary

ID

NL-OMON52438

Source
ToetsingOnline

Brief title
EBUS Acquire** Needle trial

Condition

- Respiratory tract neoplasms

Synonym
Lungcancer, staging mediastinum

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diagnosis, EndobronchialUltrasound, lung cancer, staging

Outcome measures

Primary outcome

Primary endpoint:

1. The suitability rate for the assessment of PD-L1 expression on the cell block preparation with the EBUS/EUS-B 22 G TBNB Boston Acquire** needle vs 22 G TBNA Boston Scientific standard needle of mediastinal/hilar nodal or tumor aspirates in patients with a final diagnosis of lung cancer. Cell block specimens will be considered suitable if more than 100 tumor cells are present in the specimen.

Secondary outcome

1. Cumulative length tissue core

2. Suitability for molecular analysis/next generation sequencing of 22 G TBNB vs 22 G TBNA needles

3. Sample adequacy(defined as the presence of lymphocytes or atypical cells or other pathognomic characteristics (e.g. granulomas))

4. Sample quality using Mair*s objective scoring system

5. Sample bloodiness

6. 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)

7. 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)

8. 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)

9. Complication rate

10. Procedure duration

11. Endoscopist satisfaction of needle use

Study description

Background summary

Lung cancer is the most commonly diagnosed cancer with the highest mortality worldwide. Accurate diagnosis and staging are important because it directs treatment and
prognosis. Staging the mediastinal and hilar lymph nodes is key in this process and can be done with relatively high accuracy by EBUS-TBNA and EUS-(B)-FNA. The need for high quality cytology samples for molecular analysis is growing as endosonography is often the single test to confirm malignancy. However, current available standard 22 G needles have limitations in obtaining tissue core/histology samples needed for optimal molecular subtyping of lung cancer. Recently, a dedicated fine biopsy needle (FNB) with a three-pronged cutting edge has been developed to procure histology (22 G Franseen biopsy (Acquire** needle, Boston Scientific)).

Study objective

To determine if EBUS / EUS-B guided nodal/lung tumor sampling with 22 Gauge (G) TBNB (Acquire**) needles results in improved tissue core sample acquisition in comparison to standard 22 G TBNA needles for the diagnosis and staging of lung cancer.

Study design

Investigator-initiated, international randomized controlled multicentre clinical trial including university and general hospitals.

Intervention

Endosonography will be performed under sedation following the institutional practices; commonly either propofol or low dose midazolam/fentanyl sedation will be used. All patients will undergo a systematic endosonographic evaluation of all accessible mediastinal/hilar nodes. Following the endosonographic inspection, nodes will be sampled from N3 to N2 to N1 to the tumor itself. The aspirates will be processed for both tissue core analysis, cytology smears and cell block analysis. Cytology staining and cell block preparation will be performed following the local practice. The local pathologist will analyze aspirates, including molecular analysis when indicated. For study purposes, pathology samples will be digitalized, and will be reviewed by blinded reference pathologists.

Study burden and risks

no other complication than the normal procedure with the 22 G needle

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients with (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:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2019
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Acquire Needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2021
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
Other	nl 7701
CCMO	NL68824.018.19