Needle based CLE -EBUS guided- for diagnosis and staging of lung cancer

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To assess the feasibility and safety of bronchoscopic/endosonography guided needle based confocal laser endomicroscopy patients with suspected or proven lung tumor and/or mediastinal/hilar lymph node metastases

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON48172

Source
ToetsingOnline

Brief title
nCLE in lungcancer

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lung cancer, mediastinal metastases

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Mauna Kea technologies

Intervention

Keyword: bronchoscopy, confocal laser endomicroscopy, EBUS, lungcancer

Outcome measures

Primary outcome

- To test the feasibility and safety of bronchoscopic/endosonography guided

nCLE

Secondary outcome

- Assess the diagnostic value of bronchoscopy/endosonography guided nCLE

- Develop an CLE image atlas for malignant characteristics in mediastinal/hilar

lymph nodes and peripheral lung tumors.

- Differentiate tumor types based on in-vivo characteristics of nCLE

Study description

Background summary

With an incidence of 2 million cases and 1.7 million deaths, lung cancer is amongst the commonest and deadliest cancer worldwide. To provide optimum care it is essential that the lung cancer is staged accurately. In case of a resectable primary tumor and no distant metastases, mediastinal nodal involvement directs treatment. Routinely use of CT-thorax, CT-abdomen and PET-CT has improved the detection of primary tumors and metastases but the accuracy is still suboptimal. Tissue analysis by cytology or histology is still required to confirm or disprove malignancy.
Conventional bronchoscopy has its limitations in lung cancer diagnosis. To date, with the implementation of endosonographic biopsy techniques (endobronchial ultrasound with transbronchial needle aspiration(EBUS-TBNA) and esophageal ultrasound with fine needle aspiration (EUS-FNA) showed to be a valuable and safe alternative.
By EUS and EBUS central tumors and all lymph node stations, except voor the para-aortal lymph nodes, can be reached. A radial EBUS (r-EBUS) which uses a rotating ultrasound transducer can also reach the peripheral lung tumors.
EBUS-TBNA is minimal invasive and low in costs, and although it has a good record in detecting diseases, it has limitations in excluding diseases (missing

metastases).
With the upcoming lang cancer screening and robot guided bronchoscopy techniques, the demand for direct feedback about the malginant status is higher than ever.
Needle based confocal laser endomicroscopy (nCLE) is a modern imaging technique, compatible with the conventional diagnostic aspiration needle, that uses an excitation laser light to create *real-time* microscopic images of tissues. Therefore this technique provides additional information regarding the nodal status and could therefore improve the diagnostic yield of EBUS-TBNA. In a very recent article called 'Needle-based confocal laser endomicroscopy (nCLE) for the real-time diagnosis and staging of lungcancer' Wijmans/Annema et al. proved that nCLE-EUS-FNA could identify malignant cell by three characteristics. These characteristics were described as enlarged cells, darm clumps and directional streaming.
At that time they only investigated nCLE in combination with EUS because the nCLE probe could not fit the EBUS needle. In this moment a new EBUS needle is available and will fit the nCLE probe. Until now no research had been done in the field of nCLE-EBUS-TBNA. Improved characterization of mediastinal/hilar nodes and lung lesions might lead to improved diagnosis. Ideally in the future a target lesion is investigated and immediate bronchoscopic treatment can be performed.

Study objective

To assess the feasibility and safety of bronchoscopic/endosonography guided needle based confocal laser endomicroscopy patients with suspected or proven lung tumor and/or mediastinal/hilar lymph node metastases

Study design

This is a single-center observational study. Forty patients with a suspicion of a lung tumor and/or mediastinal/hilar lymph node metastases will be included. These patients already have an indication for bronchoscopy/endosonography and will additionally receive nCLE measurements. By including forty patients we expect to have at least 30 malignant samples to investigate. According to the IDEAL-guidelines for the implementation of novel techniques, 30 is enough to calculate a sample size for future studies. The reference standard will be based on the cytology results of the conventional techniques and/or the surgical pathological staging.

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Study burden and risks

Study participation includes that routine bronchoscopic/endosonography technique will be performed under deep sedation will be prolonged by a maximum

of 10 minutes during which a CLE video will be made trough the biopsy needle.
For study purposes fluorescein will be injected intravenously through a venous access with a 1,1% risk of adverse events (nausea is described).
Standard diagnostic procedures and subsequent treatment won't be affected by the study participation. In our opinion we judge the burden and risk of study participation to be neglectable.

Contacts

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Eligibility criteria

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

Inclusion criteria

- >18 years of age
- Suspected or tissue proven lung tumor and/or suspected malignant mediastinal/hilar lymph nodes within reach of EBUS-TBNA

Exclusion criteria

- Inability and willingness to provide informed consent
- Inability to comply with the study protocol
- Patients with known allergy for fluorescein or risk factors for an allergic reaction:
- use of betablokker within 24 hours before start of the EBUS-TBNA procedure

- possible pregnancy or lactating women

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):	06-05-2019
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	needle based confocal laser endomicroscpy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-04-2019
Application type:	First submission
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	NL68592.018.18