Needle based confocal laser endomicroscopy for the diagnosis and staging of lung cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21898

Source
NTR

Brief title
nCLE lung cancer

Health condition

Lung cancer

Sponsors and support

Primary sponsor: Investigated initiated research sponsored by Mauna Kea technologies (Paris, France)
Source(s) of monetary or material Support: Mauna Kea Technologies, Paris

Intervention

Outcome measures

Primary outcome

Feasibility (>80% of the tumor/node needle aspirates it is possible to obtain adequate CLE video footage of the target lesion) and safety (no adverse events related to the nCLE

measurements) of bronchoscopic/endosonographic (EBUS/EUS-B) guided nCLE

Secondary outcome

- Create a nCLE image atlas for malignant characteristics in lung tumors and mediastinal/hilar lymph nodes.
- Differentiate lung tumor subtypes based on in-vivo characteristics of nCLE
- Assess the diagnostic value bronchoscopic/endosonographic-guided nCLE

Study description

Background summary

Needle based confocal laser endomicroscopy (nCLE) is a high resolution imaging technique, compatible with the conventional diagnostic aspiration needles, that uses an excitation laser light to create 'real-time' microscopic images of tissues. nCLE provides real-time information of the tissue at the needle tip (smart needle). Bronchoscopic/ EBUS guided nCLE of lung tumors and intrathoracic nodes will be performed with the aim to describe CLE-characteristics for lung tumor subsets. Real-time diagnosis and staging of lung cancer might be important for future lung nodule/ staging strategies.

Study objective

We hypothesize that bronchoscopic/endosonographic (EBUS/ EUS-B) guided nCLE-imaging of lung tumors/ nodes followed by tissue sampling for the diagnosis and staging of lung cancer is feasible and safe.

Study design

2 years

Contacts

Public
Amsterdam UMC, locatie AMC, afdeling Longziekten
Marianne van de Pol

+31 (0)20 566 1285
Scientific
Amsterdam UMC, locatie AMC, afdeling Longziekten
Marianne van de Pol

+31 (0)20 566 1285

Eligibility criteria

Inclusion criteria

>18 years of age, (suspected) lung cancer and/or malignant mediastinal/hilar lymph nodes

Exclusion criteria

- Inability or non-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 beta-blocker within 24 hours before start of the bronchscopic/endosonographic procedure
- pregnancy or lactation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	04-06-2019
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	NL7780
Other	METC Amsterdam UMC, location AMC : METC 2018_335

Study results