CLE in diagnosing pleural malignancies, a comparison with pathology

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To describe criteria on CLE-imaging of different entities (thoracic wall/ pleura/ fibrosis/ mediastinum) compared to histology.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mesotheliomas
Study type	Observational invasive

Summary

ID

NL-OMON45606

Source
ToetsingOnline

Brief title
CLE for diagnosing pleural malignancies

Condition

- Mesotheliomas
- Pleural disorders

Synonym
mesothelioom, Pleural thickening

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CLE, mesothelioma, pleural malignancies

Outcome measures

Primary outcome

- To describe and develop visual descriptive image criteria for CLE images of malignant, normal and fibrotic areas (thoracic wall, pleura, mediastinum)

- To obtain quantitative measures by CLE imaging of these malignancies

Secondary outcome

- Assessing technical feasibility of CLE by several approaches used in the process of diagnosis or staging (% of successful videos/time for procedure (min))

- Assessing procedure-related adverse events of CLE in this group of patients

Study description

Background summary

Novel optical imaging techniques such as confocal laser endomicroscopy (CLE) have emerged in recent years as techniques that actually enable in vivo real-time microscopic analysis of malignancies of the GI-tract and lung cancer (1,2,3). Through recent advances the probe became small enough to fit through a biopsy needle and can be used during CT-guided (3) and endosonographic guided biopsies (EUS-FNA)(1,2). Since the first trimester of 2016 our research group in the AMC is performing needle based CLE for lung cancer (Clin trial gov NCT02689050), with promising results7. As a result, expansion of this innovative technique to other intra-thoracic malignancies during biopsy procedures seems a logical next step. Patients with intra-thoracic malignancies often require invasive procedures such as bronchoscopy, thoracoscopy, mediastinoscopy trans thoracic needle aspiration or surgical exploration to obtain a diagnosis. Intra thoracic malignancies encompass lung cancers, thymomas and malignant pleural mesothelioma. These tumors often present with pleural thickening, unilateral pleural effusion, mediastinal enlargement or a peripheral located mass in the lungs. Tissue collection of the suspected

pleural thickening is required to assess a diagnosis and differentiate between the tumor types, to classify and to stage in a proper manner. To date, the different biopsy methods, such as CT-guided pleural biopsy, mediastinal biopsy, endosonography and thoracoscopy have their limitations in diagnosing these malignancies. Sampling errors frequently occur resulting in the common histological finding of *non-specific pleuritic/fibrosis*, which presents a great uncertainty for clinicians and patients.11 Novel microscopic imaging techniques such as CLE seem to be capable of distinguishing areas of fibrosis from malignant tumors involved in lung cancer14, however data in other intra-thoracic malignancies are lacking. Therefore the aim of this study is to investigate whether CLE can:
1. Provide real time information of the biopsy location during diagnostic biopsies in patients with suspected pleural lesions encompassing mesothelioma, thymoma and other tumors
2. Improve the diagnostic yield of tissue-biopsies.

Study objective

To describe criteria on CLE-imaging of different entities (thoracic wall/ pleura/ fibrosis/ mediastinum) compared to histology.

Study design

This is a multi-center (NKI and AMC), investigator-initiated, observational study. A maximum of 20 patients with (a strong suspicion of) an intra-thoracic malignancy are enrolled. All of the enrolled patients have an indication for tissue collection (by transthoracic CT/US- guided biopsy, E(B)US, mediastinoscopy or thoracoscopic guided biopsy).

Study burden and risks

A participating patient will not benefit from this study. However the results of this study may benefit the diagnostic procedure of future intra thoracic (mesothelioma) diagnostics and may improve quality of life of future patients, by lowering the number of biopsies. The procedure of needle based CLE combined with endosonographic- and transthoracic- tissue biopsy have proved to be safe and provides real time information on a microscopic level regarding tissue architecture3,4,7,16. There is little burden related to study participation: during a conventional biopsy procedure (e.g. endosconographic-, transthoracic- or thoracoscopic biopsy), optical CLE with the use of a light beam will be performed by fitting the CLE probe through the biopsy needle and bringing it in perpendicular contact with the tissue. This is followed by conventional biopsy of the tissue (routine work up) at the same site as the CLE measurements, without the need for additional biopsies for research purposes. Estimated prolonged procedure time due to imaging is 5 (for transthoracic approaches, under local anesthesia) to 10 minutes (for EUS and thoracoscopy approaches,

with propofol-sedation or general anesthesia). Adverse events are not expected, based on our own CLE experience in patients with interstitial lung diseases (Clintrial.gov identifier NCT02689102, NL54612-018-15), lung cancer and sarcoidosis (Clintrial.gov identifier)(Clinicaltrial.gov identifier NCT NCT02689050, protocol nr NL54612-018-15), and the data of previous studies where CT-guided transthoracic biopsies combined with CLE was reported to be safe, easy to perform and little time-consuming, without adverse events related to CLE. In conclusion, to our opinion the burden and risks associated with the additional optical technique measurements are neglectible.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-*18 years of age

-Supected intra-thoracic malignancies with pleural involvement and referred for a diagnostic procedure by thoracoscopy, transthoracic biopsy or endosonography.

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 12 hours before start of the procedur
- 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):	28-08-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Confocal Laser Endomicroscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-03-2017

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	NL60800.018.17