Needle based CLE in thoracic lymph nodes, a comparison with pathology.

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To identify and define characteristics of healthy lymph nodes and lymph nodes involved in different pulmonal diseases (lungcancer and sarcoidosis)

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

Summary

ID

NL-OMON43854

Source
ToetsingOnline

Brief title
Needle based CLE in thoracic lymhp nodes.

Condition

- Lymphomas NEC
- Respiratory tract neoplasms

Synonym
Intrathoracic lymphadenopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,legaat tbv endoscopie-onderzoek via AMR

Intervention

Keyword: CLE, lymph nodes, needle based

Outcome measures

Primary outcome

1 To describe characteristics and define interpretation criteria for nCLE

imaging of:

- normal/reactive lymph nodes

- lymph nodes involved in lungcancer

- lymph nodes involved in sarcoidosis

Secondary outcome

1. To develop an CLE image atlas for lymph nodes involved in different pulmonal

diseases

2.To assess procedure-related events of needle based CLE

3. To assess technical feasibility of needle based CLE

Study description

Background summary

The current minimal-invasive techniques for assessing mediastinal lymph nodes have limitations, therefore surgical procedures are often indicated when a diagnosis can not be established after an endoscopic procedure. Confocal laser endomicroscopy is a novel imaging technique, that can be advanced trough a biopsy needle and is capable of showing real-time images of tissues on a microscopic level, during an EUS-FNA procedure. CLE is a novel technique and the obtained images need to be defined and classified for different pulmonal diseases that present with lymphadenopathy.

Study objective

To identify and define characteristics of healthy lymph nodes and lymph nodes

involved in different pulmonal diseases (lungcancer and sarcoidosis)

Study design

This is an investigator-initiated, observational study in 20 patients. In 10 patients with NSCLC with suspected malignant lymphnodes and an indication for EUS-FNA and 10 patients with suspected sarcoidosis stage I-II and an indication for EUS-FNA.

Study burden and risks

A participating patient will not benefit from this study. However the results of this study may benefit the diagnostic EUS-FNA procedure in mediastinal lymph nodes and could make invasive biopsies and surgical procedures redundant. Needle based CLE in combination with EUS has proved to be a safe, minimally invasive imaging technique that in conjunction with conventional endosonographic procedures can provide real-time information on a microscopic level. There is little burden related to study participation: before the start of the procedure a contrast-agent (fluorescein) will be administered intravenously via the same entrance as the sedative-medication is provided. For this reason patients won't undergo an extra venous puncture for study purposes. We excluded patients with increased risk for allergic reactions to fluorescein and therefore think that the risk of administering fluorescein is neglectable. Furthermore two CLE measurements of lymph nodes will be conducted during the EUS-FNA procedure, no additional risks are expected as no additonal tissue will be removed and there is no risk of radiation. Estimated prolonged endoscopy time for imaging is 5 minutes. The patient will not notice anything due to propofol sedation. Adverse events are not expected , based on previous studies where EUS-FNA combined with needle based CLE and the administration of fluorescein is reported to be safe, easy to perform and little time consuming, without adverse events. In conclusion we believe that the burden and risks associated with the additional CLE measurements are low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- suspected or proved NSCLC, with an indication for EUS-FNA for tissue verification of suspected mediastinal lymph nodes.
- Suspected sarcoidosis stage I-II, with an indication of tissue verification of enlarged mediastinal lymph node(s) by EUS-FNA.

Exclusion criteria

- Allergy for fluorescein
- Use of Beta blocker on the day of the procedure
- (Possible) pregnancy or lactation
- Inability to provide informed consent
- Inability to comply with study protocol

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):	13-01-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	26-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2016
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
CCMO	NL54080.018.15