Spectroscopy in lymph nodes during Endoscopisch Ultrasound-Fine Needle Aspiration (EUS-FNA) procedure in patients with lung cancer

Published: 12-02-2008
Last updated: 10-05-2024

Development of a new technics to improve the diagnostic value of an EUS procedure in combination with reducing the amount of biopsies.

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

Summary

ID

NL-OMON31443

Source
ToetsingOnline

Brief title
Spectroscopy in lymph nodes

Condition

- Respiratory tract neoplasms

Synonym
lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EUS, Lymph nodes, Spectroscopie

Outcome measures

Primary outcome

1. Is there a difference in spectroscopic spectra between malignant and benign

lymph nodes?

Secondary outcome

2. Is it possible to improve the diagnostic value of an EUS procedure using

reflectance spectroscopy?

Study description

Background summary

Lung cancer is the second most common cancer in men and women, and is the leading cause of cancer related death. In industrialized countries it kills more patients than breast, colorectal and prostate cancer combined. Treatment and prognosis are depended on stage. During lung cancer staging analysis, information about the possibility of metastasis in mediastinal lymph nodes is very important. Recent development makes it possible to examine mediastinal lymph nodes by Endoscopisch Ultrasound-Fine Needle Aspiration (EUS-FNA) procedure. Unfortunately, ultrasound sensitivity to detect positive lymphnodes is poor, and therefore cytology must always be obtained. Transoesophageal ultrasound fine needle aspiration will take place to obtain tissue, which will send to the pathologist for further analysis.
Although this take place under echographic vision, it is not possible to know which part of a lymph node has the highest chance to obtain a positive result. To reduce the chance of false negative results a lymph nodes must be aspirated many times. This makes an EUS procedure long and expensive. Even when a pathologist examin the samples, right after the procedure, false negative result are possible. After a negative EUS procedure, a mediastinoscopy must be carry out, is still nowadays concensus. This procedure is must more invasive, and the risk of complication is higher.

Study objective

Development of a new technics to improve the diagnostic value of an EUS procedure in combination with reducing the amount of biopsies.

Study design

The method to measure optical properties in vivo with the use of diffuse reflectance measurements has been documented in literature. As light source, we use a xenonlamp and for the detection of reflected light a 2-canal spectrograph. The transport of light from the light source to the tissue and reflected light back to the spectrograph is by a 5 meters length glass fibre. Because of this long glass fibre length, the measurement equipment can positioned at a save distance of the EUS-FNA equipment.
During Endoscopic Ultrasound Fine Needle Aspiration (EUS-FNA) procedure a gastroscope is introduced in the oesophagus. With help from an echo located at the distal end of the scope, suspected lymph nodes are detected and a standard EUS-FNA needle is conducted to the mediastinal lymph nodes. The sterile biopsy needle is positioned in a mediastinal lymph node and the working guide wire, which is in the needle core, is removed. A sterile fiberoptic probe is inserted through the now empty working cannel of the biopsy needle in the lymph node and a measurement is performed. After the fiberoptic probe is removed from the needle, cytological tissue can be obtained. To prevent risk of ent-metastasis or diagnostic misleading, measurements take place by standard EUS-FNA procedure. This implies measurements starting in lymph nodes N3 then N2 and finally N1.
The cytological result will be correlated to the spectral results, which are collected with the sterile fiberoptic probe.

Study burden and risks

A file with the required records is present and available for examination.
The following security supplies
a) Optical
The light intensity of the optical fibres is less than 200 µWatt. This is far below the threshold for thermal damage of the patients lungtissue and the eyes of the supportive staff. Other damage have not been confessed in this golf length area.
b) Hygiene
The disposables optical fibers are made especially for this research and supplied sterile.

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

Patients highly suspect or diagnosed with lungcancer, with enlarged mediastinal lymphnodes, suspect for lymph nodes metastasis, where an EUS procedure is necessary for a diagnosis

Exclusion criteria

Esophagus strictures
History of evidence of inherited bleeding diathesis or coagulopathy with the risk of bleeding

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-08-2008
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO

Date:	12-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL18312.078.07