Single centre study comparing results of pathologic analysis of EUS-FNA with EUS-TCB in patients with enlarged mediastinal lymph nodes.

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Primary Objective: The primary objective is to investigate whether EUS-TCB had an added value on EUS-FNA alone. Secondary Objective(s): The secondary objective is to study whether EUS-TCB does not have a higher complication rate than EUS-FNA alone...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lymphomas NEC
Study type	Interventional

Summary

ID

NL-OMON35501

Source
ToetsingOnline

Brief title
EUS-FNA vs EUS-FNA and EUS-TCB

Condition

- Lymphomas NEC
- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lymph node enlargement; indication for diagnosis

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Intern binnen het ziekenhuis

Intervention

Keyword: diagnosis, EUS-FNA, EUS-TCB, pathology

Outcome measures

Primary outcome

The main study endpoint will be the difference between EUS-FNA alone and

EUS-FNA and EUS-TCB.

Secondary outcome

The secondary endpoint will be the amount of adverse events seen with the

procedure like bleeding and mediastinitis.

Study description

Background summary

Endoscopic ultrasound guided fine-needle aspiration is a widely used diagnostic tool in the analysis and staging of lung cancer and mediastinal lymphadenopathy in other diseases. Lymph nodes are easily accessed with this method at locations near the oesophagus. Locations high paraoesophageal (Naruke 2), aorto-pulmonary window (Naruke N4L), subcarinal (N7) and low paraoesophageal (Naruke 8 and 9) can be reached.
EUS-FNA has a sensitivity of 88-96% and a specificity of almost 100% and an accuracy of 95%.
In the gastroenterology trucut biopsy (EUS-TCB) is a proven diagnostic tool in the evaluation of benign and malignant disease, as well as in staging malignant tumours of the gastrointestinal tract.
In mediastinal lesions too EUS-TCB is an accurate method. There is a diagnostic accuracy of 90% and in combination with EUS-FNA 98%. EUS-TCB is as safe as EUS-FNA when used in the stomach, with a complication rate of 2%.
However limitations of these studies are that they were retrospective studies. Therefore a prospective study has to be performed to see if EUS-TCB has an

added value to EUS-FNA alone.

Study objective

Primary Objective: The primary objective is to investigate whether EUS-TCB had an added value on EUS-FNA alone.
Secondary Objective(s): The secondary objective is to study whether EUS-TCB does not have a higher complication rate than EUS-FNA alone.

Study design

A single centre prospective accuracy study will be performed.
The study will be carried out between October 2011 and May 2012.
All patients who have to undergo an EUS-FNA and have lymph nodes larger than 20mm on CT will be asked to undergo EUS-TCB also. When lymph nodes are also larger than 20mm at ultrasound too, EUS-TCB can be performed.
During EUS the complications will be scored.
The pathologist will try to give a diagnosis on the EUS-FNA alone and on EUS-TCB alone.

Intervention

The intervention of this study is to perform trucut biopsy (TCB). There will be performed 4 passes for histologic material. This will be done by using the Quick core endoscopic ultrasound biopsy needle of 19 GA (Cook Ireland Ltd).

Study burden and risks

There seems to be no increased risk compared to standard procedure in previous investigation. The increase in time for the patient in the study, takes about 5 minutes.
There propably can be given a better diagnose on the lymph node enlargement due to histologic biopsies.

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 with large mediastinal lymph nodes (>2cm) at location Naruke 7 or Naruke 4 Left on CT or PET-CT.
Enlarged lymph nodes on EUS more than 2cm.
Age 18 and older.
ASA classification 1 - 3
Informed consent

Exclusion criteria

ASA classification > 3
Obstructing oral or laryngeal disease.
Severe maxillofacial deformity

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2011
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	trucut biopsy needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-12-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL38098.075.11