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

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To compare the feasibility of mutation analysis in samples obtained with EUS-FNA and EUS-TCB in patients with mediastinal lymph node metastasis in NSCLC. To compare EUS-TCB with EUS-FNA in diagnosing benign and malignant mediastinal disease.

Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON35924

Source
ToetsingOnline

Brief title
Assessment of EUS-FNA compared to EUS-FNA and EUS-TCB.

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
enlarged lymfnodes and malignancy

Research involving

Human

Sponsors and support

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

Intervention

Keyword: diagnosis, EUS-FNA, EUS-TCB, mutation analysis

Outcome measures

Primary outcome

Pathologic diagnosis; mutation analysis in NSCLC

Secondary outcome

Complications

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.
EUS-FNA has a sensitivity of 88-96% and a specificity of almost 100% and accuracy of 95%1, 2 .
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 3.
In mediastinal lesions too EUS-TCB is an accurate method. There is a diagnostic accuracy of 98% in combination with EUS-FNA 4.

Molecular analysis for EGFR and KRAS mutations evolved to increasing relevance and is rapidly developing to standard practice in stage IV NSCLC5. Most mutation analysis has been done on histologic samples, however more and more studies report on molecular diagnostics on cytological material too (using High resolution melting6), it is not clear if this method has a better specificity and sensitivity than mutation analysis on histological material.

In this study the pathologic results of histologic and cytologic samples of

mediastinal lymph nodes obtained with EUS-TCB respectively EUS-FNA are compared in order to evaluate the added value of histology in the diagnosis of malignant and benign mediastinal disease.
Moreover the feasibility of molecular analysis in EUS-TCB and EUS-FNA derived samples is compared for patients with a diagnosis of NSCLC.

We also want to score the complication rate. In the gastroenterology a complication rate of 2% is described in EUS-FNA as in EUS-TCB (infection and bleeding)7.

Study objective

To compare the feasibility of mutation analysis in samples obtained with EUS-FNA and EUS-TCB in patients with mediastinal lymph node metastasis in NSCLC.

To compare EUS-TCB with EUS-FNA in diagnosing benign and malignant mediastinal disease.

Study design

Prospective, open, single-arm, single-centre trial

Study burden and risks

Little additional load (the test takes around 5minuten longer) plus additional punctures, which are generally not felt.

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

1. Patients with large mediastinal lymph nodes (>2cm) at location N7, N4L on CT or PET-CT.
2. Age of 18-85 years.
3. ASA classification 1 - 3

Exclusion criteria

1. ASA classification > 3 (see appendix A)
2. Obstructing oral or laryngeal disease.
3. Severe maxillofacial deformity.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	102
Type:	Anticipated

Ethics review

Not approved

Date:	24-05-2011
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	NL36627.075.11