Rapid on-site evaluation (ROSE) vs. randomly collected samples from mediastinal and abdominal lymph nodes obtained by endoscopic ultrasound-guided fine-needle-aspiration

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The goal is to investigate the added value of having a cytotechnician on-site while performing EUS-FNA of a lymph node.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON45053

Source
ToetsingOnline

Brief title
ROSE-study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Enlarged lymph nodes, lymphadenopathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diagnostic yield, EUS-FNA, lymph nodes, Rapid on-site evaluation

Outcome measures

Primary outcome

The primary parameter is the percentage of cases in which the cytopathologist can make a diagnosis on the contents of the lymph node, based on the EUS-FNA samples of the lymph node. (=diagnostic yield)

Secondary outcome

-Diagnostic accuracy

-Sensitivity, specificity, negative predictive value and positive predictive value of a certain number of needle passes in both groups.

-Judgment of the cytotechnician on-site and the cytopathologist of each sample

-Number of needle passes required per case according to the cytotechnician on-site and according to the cytopathologist in both groups.

-Time required in both groups.

-Cost-effectivity of both approaches.

-Number and nature of complications in both groups.

Study description

Background summary

Endoscopic ultrasound (EUS) is a widely used, minimally invasive and safe

method for imaging mediastinal and abdominal lymph nodes. A major advantage of EUS is that interventions such as fine needle aspiration (FNA) are possible during the procedure. FNA adds the ability to take lymph node samples and to reach a definitive diagnosis based on cytology, histological tissue samples or a combination of both. FNA has changed EUS from a highly subjective imaging modality in a more objective diagnostic procedure. EUS-FNA is used for diagnosing and staging abdominal and mediastinal tumors and benign diseases such as sarcoidosis and reactive lymphadenopathy. The high sensitivity, high accuracy and low complication risk has led to an increasing number of gastroenterologists performing EUS-FNA in daily practice.
There is an ever present ambition to optimize the diagnostic yield of EUS-FNA, a representative sample of the contents of the lymph node is essential for making a diagnosis. Therefore, many studies have been conducted with the emphasis on increasing the yield of diagnostic EUS-FNA through the optimization of different aspects of the process. One aspect that has been investigated by several studies is the addition of direct on-site evaluation, although these were mainly retrospective studies. Several approaches have been used to assess the benefit of either a cytopathologist or a cyto-analyst spot. The idea is that having a cyto-analyst on site is useful to give feedback and advice to the endosonografist if necessary. It is thought that this reduces the number of non-diagnostic procedures. However, study results are contradictory.

Study objective

The goal is to investigate the added value of having a cytotechnician on-site while performing EUS-FNA of a lymph node.

Study design

This is a multi-center, prospective, single-blinded, randomized controlled trial. In the random sample group, the endosonographer is blinded to the evaluation of the cytotechnician. The cytopathologist that later re-analyzes the samples (in the context of the study, not daily practice) is blinded to the evaluation of the cytotechnician and to the diagnostic group of the patients, which means that the samples will be evaluated sequentially without any further information on how many needle passes were performed. The results of the EUS-FNA will be compared to the final diagnosis. The definitive diagnosis is based on histology of the lymph nodes or clinical follow-up of at least 6 months or until death.

Study burden and risks

EUS-FNA is a safe procedure. Complications occur in 0-1%. Although hypothetically an increased number of needle passes could increase the risk of complications, no such correlation has ever been established. Patients are sedated during the EUS-FNA and therefore do not experience more discomfort in

either group. Standard of care is provided. Post-procedural treatment does not differ between the two groups. There is no direct benefit for patients participating in this trial.

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

>=18 years old
Scheduled to undergo endoscopic ultrasound (EUS) with fine-needle aspiration (FNA) of a lymph node in either the mediastinum or the abdomen
Written informed consent

Exclusion criteria

Patients with a poor mental condition or mental retardation, unable to understand the nature and possible consequences of the study
Coagulopathy (INR>1.5, platelets<50.000/mm3) which has not been corrected prior to the procedure
Pregnancy
Previous participation in this trial

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2014
Enrollment:	244
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-06-2014

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-08-2016
Application type:	Amendment
Review commission:	METC NedMec

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	NL45282.041.13