Forward viewing US endoscope versus standard oblique viewing US endoscope in the performance of EUS-guided fine needle aspiration of solid lesions of the gastrointestinal tract and of adjacent organs: A prospective randomized controlled study

Published: 24-10-2012
Last updated: 26-04-2024

The primary aim of the study is to compare the performance of the standard oblique-viewing US endoscope versus a prototype forward viewing ultrasonic endoscope for EUS-FNA of solid lesions of the GI tract and of adjacent organs.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON37177

Source
ToetsingOnline

Brief title
FoOb

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

mass lesions, solid lesions

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Endosonography, FNA, Gastrointestinal tract

Outcome measures

Primary outcome

* Successful lesion identification

* Technically successful EUS-FNA by EUS image confirming the needle into the lesion

* Diagnostically successful EUS-FNA by obtainment of adequate material for analysis

Secondary outcome

* Comparison of the performance (sensitivity, specificity, and diagnostic accuracy) of the two different EUS scopes for EUS-FNA

* Ease of procedure

* Procedure related complications

Study description

Background summary

Since its initial report in 1992, endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has been incorporated in diagnostic algorithms for the evaluation of solid and cystic lesions of the gastrointestinal (GI) tract and

of adjacent organs. The expansion of EUS-FNA has been largely stimulated by the introduction of linear-array echoendoscopes that made possible to follow the full course of the needle from its exit from the instrument to its entrance in the target lesion under real-time US guidance. Until now, all the available linear echoendoscopes utilized to perform EUS-FNA have been curved linear scopes (CLA-EUS) which are characterized by an oblique endoscopic view, 55o rotated respect to the scope axis and the ultrasonographic probe, and by the exit of the FNA needle that occurs with an oblique angle from the side.
Recently, a forward viewing linear echoendoscope (FV-EUS) has been developed with the aim of potentially expanding the therapeutic applications of EUS.
This prototype is a modification of the CLA scope and it is characterized primarily by a shifting of the orientation of the endoscopic and US views from oblique to forward. The US transducer is located adjacent to the working channel, at the endoscope tip, to display a forward-viewing image along to a scanning plane that is parallel to the insertion direction with a 90° scanning range. It has a 3.7 mm working channel without elevator, which allows exit of the FNA needle or any other accessory used parallel to the longitudinal axis of the scope.
Preliminary experiences with this scope have reported potential advantages over the conventional linear scope (CLA-EUS) for pseudocysts drainage and for hilar biliary strictures. Moreover, a large experience still unpublished from the Catholic University, Rome, Italy in the use of the FV-EUS for FNA of solid and cystic lesions throughout the GI tract has shown the FV-EUS to be highly effective with a performance that seems at least comparable to that of the CLA-EUS. To date, however, no data comparing the performance of both scopes for FNA of target lesions are available to better clarify the advantages and disadvantages of one scope over the other.

Study objective

The primary aim of the study is to compare the performance of the standard oblique-viewing US endoscope versus a prototype forward viewing ultrasonic endoscope for EUS-FNA of solid lesions of the GI tract and of adjacent organs.

Study design

multicenter, prospective randomized controlled trial

Intervention

Each patient will undergo examination with the CLA-EUS or the FV-EUS, which will be selected based on the randomization process. FV-EUS will be performed using the newly available FV *EUS scope (TGF-Y0001-UC) that is compatible with last generation Aloka alpha 10. First, search of the presumed lesion will be performed and once visualize, its characteristics (size, echogenicity, margins, etc) will be recorded on data collection sheet. Fine needle aspiration will be

performed under EUS guidance using a 19- ,22- or a 25-gauge fine needle or procore needles depending on endoscopist*s preference . In case an on-site cytophatologist will not be available, a minumum of 3 needle passes for lymph nodes and 5 needle passes for solid lesions per patient will be performed.
Picture of the visualized lesion and of the needle inside the lesion till be taken and stored to prove visualization and puncture of the target lesion.
In case the lesion can not be found or successfully punctured with endoscope selected based on the randomization this scope will be withdrawn and the other (nonrandomized endoscope) will be introduced contiguous

Study burden and risks

Because sampling of the solid lesions in the GI tract or in one of the adjacent organs will be indicated in all patients, the extra burden will be limited. There will be a small chance that identification and/or FNA of the target lesion is not successful with the prototype forward viewing US endoscope. Consequently, the procedure need to be repeated with a standard oblique viewing endoscope, which will be done contiguous. On the other hand, it may happen that target lesion can be visualized and/or punctured with the forward viewing and NOT with the standard oblique viewing, and participating in this study may appear to be beneficial.

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

Presence of a solid lesion in the GI tract or in one of the adjacent organs identified at abdominal US, CT, MRI/MRCP that needs to be samples with endoscopic ultrasonographic fine needle aspiration (EUS-FNA).

Exclusion criteria

Patients with active coagulopathy that cannot be corrected after administration of plasma

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Endoechoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-10-2012
Application type:	First submission
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
ClinicalTrials.gov	NCT01673945
CCMO	NL40619.018.12