ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 01/25/2017 11:07

ClinicalTrials.gov ID: NCT02360839

Study Identification

Unique Protocol ID:	Dnr 1092-11
Brief Title:	The Use of FNA and FNB in the Optimization of EUS-assisted Tissue Sampling
Official Title:	The Use of FNA and FNB in the Optimization of EUS-assisted Tissue Sampling
Secondary IDs:	

Study Status

Record Verification:	January 2017
Overall Status:	Recruiting
Study Start:	July 2009 []
Primary Completion:	July 2017 [Anticipated]
Study Completion:	July 2019 [Anticipated]

Sponsor/Collaborators

Sponsor:	Per Hedenström
Responsible Party:	Sponsor-Investigator Investigator: Per Hedenström [phedenstrom] Official Title: Dr Affiliation: Sahlgrenska University Hospital
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
IND/IDE Protocol:	No
Human Subjects Review:	Board Status: Approved Approval Number: Dnr 1092-11 Board Name: Regionala Etikprövningsnämnden i Göteborg Board Affiliation: Centrala etikprövningsnämnden, Vetenskapsrådet Phone: +46 31 786 68 22 Email: barbro.morsing@gu.se Address: Regionala Etikprövningsnämnden i Göteborg (Regional Ethical Review Board)

Att: Barbro Morsing
Box 401
S-405 30 Göteborg
SWEDEN

Data Monitoring: No

Plan to Share IPD: NOTE : Plan to Share IPD? has not been entered.

FDA Regulated Intervention: No

Study Description

Brief Summary: Endoscopic ultrasound (EUS) with fine needle aspiration (FNA) for cytology and/or fine needle biopsy (FNB) for histology may be used in the diagnostic work-up of intrathoracic and intrabdominal lesion of unknown origin. Certain lesions (such as pancreatic adenocarcinoma) are often well characterized by cytology assessment of FNA-samples while others are not (such as GIST-tumors).

This study is a part observational (early study phase) and part interventional study (late study phase) on the diagnostic accuracy of EUS-assisted tissue sampling by FNA or FNB during a 10-year period on a tertiary endoscopy centre.

Detailed Description: Variables affecting the diagnostic accuracy of EUS-FNA and EUS-FNB in different cases and tumor scenarios will be studied in detail such as the influence of medical equipment used (i.e the different types and sizes of puncture needles), the experience of the endosonographers, cytopathologists and pathologists and the use of rapid on-site evaluation of cytology samples.

Each study case is reviewed post-EUS (according to the schedule precised below) regarding further diagnostic work-up, neoadjuvant treatment, surgery result, clinical follow-up, (neo)adjuvant treatment, and survival. Non-parametrical tests will be applied as the main statistical method.

Conditions

Conditions: Neoplasms

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Diagnostic

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Participant, Care Provider

Allocation: Randomized

Enrollment: 1000 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
No Intervention: Early Study subjects (patients) undergoing endoscopic ultrasound (with or without FNA/TCB) for clinical reasons during 2005-2011.	
Late Study subjects (patients) undergoing endoscopic ultrasound with EUS-guided sampling of various lesions for clinical reasons during 20012-2015. Subjects sampled with both EUS-FNA and EUS-FNB on the same lesion. Randomization on first needle order.	Device: EUS-guided fine needle biopsy sampling (EUS-FNB) Dual sampling with EUS-FNA and EUS-FNB in a randomized order.

NOTE : An arm/group label this short may not be sufficiently descriptive, especially for later use in results.

NOTE : No interventions have been included in Arm Description for 'Late'

NOTE : Intervention 'EUS-guided fine needle biopsy sampling (EUS-FNB)' has not been included in any Arm/Group Descriptions.

Outcome Measures

Primary Outcome Measure:

1. The cellular quality of the EUS-FNA specimens (categorical variable).
   Specimens are measured on a standardized 5-grade categorical scale - from 1 (=poor, non-diagnostic yield) to 5 (excellent, completely diagnostic yield). There is no specific unit measured (the variable is not a continuous one). The results from cytology assessment of EUS-derived tissue are compared to the final diagnosis, that is based on the subsequent surgery report. Results from FNA and FNB are regarded equally important. That is why both are treated as Primary Outcomes.

   [Time Frame: Follow up is by time of surgery (in average 2 months after EUS-FNA)]
2. The histological quality of the EUS-FNB specimens (categorical variable).
   Specimens are measured on a standardized 5-grade categorical scale - from 1 (=poor, non-diagnostic yield) to 5 (excellent, completely diagnostic yield). There is no specific unit measured (the variable is not a continuous one). The results from pathology assessment of EUS-derived tissue are compared to the final diagnosis, that is based on the subsequent surgery report. Results from FNA and FNB are regarded equally important. That is why both are treated as Primary Outcomes.

   [Time Frame: Follow up is by time of surgery (in average 2 months after EUS-FNB)]

Secondary Outcome Measure:

3. Immunohistochemistry profiling of EUS
   The immunohistochemical (IHC) profile of tumor material from EUS-samples will be compared to the immunohistochemical profile of tissue derived from surgery of the very same case (categorical variable, Yes (1) = correct IHC-profiling by EUS or No (2) = non-correct IHC-profiling by EUS).

   [Time Frame: Follow up is by time of surgery (in average 2 months after EUS)]

NOTE : Normally only one Primary Outcome Measure is specified.

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria: • Referral for a diagnostic EUS Exclusion Criteria: • Referral for an interventional EUS

Contacts/Locations

Central Contact Person:	Per Hedenström, Dr Telephone: +46 703 288291 Email: per.hedenstrom@vgregion.se
Central Contact Backup:	Riadh Sadik, Prof Telephone: +46 733 641355 Email: riadh.sadik@vgregion.se
Study Officials:	Riadh Sadik, Prof Study Principal Investigator Sahlgrenska University Hospital, Gothenburg
Locations:	Sweden Dr Per Hedenström [Recruiting] Gothenburg, Sweden, S-413 45 Contact: Per Hedenström, Dr +46 703 288291 per.hedenstrom@vgregion.se Contact: Riadh Sadik, Prof +46 733 641355 riadh.sadik@vgregion.se

References

Citations:	
Links:	
Study Data/Documents:	