

Fine Needle Biopsy of Solid Pancreatic Mass Lesions

ClinicalTrials.gov Identifier: NCT04085055

Recruitment Status: Recruiting
First Posted: September 11, 2019
Last Update Posted: August 5, 2020

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government.

Information provided by (Responsible Party): AdventHealth

Sponsor: AdventHealth

Study Details Tabular View No Results Posted Disclaimer How to Read a Study Record

Study Description

Brief Summary: This is a randomized trial to evaluate and directly compare the tissue quality, diagnostic success and safety profile of four different Fine Needle Biopsy needles.

Table with 3 columns: Condition or disease, Intervention/treatment, Phase. Row 1: Pancreatic Neoplasms, Diagnostic Test: Solid pancreatic mass lesion biopsy, Not Applicable.

Detailed Description: Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) is currently the standard method for sampling solid pancreatic masses...

Four different types of FNB needles are currently available - reverse-bevel tip (EchoTip ProCore HD Ultrasound Biopsy Needle, Cook Medical, Bloomington, IN), Menghini-tip (EZ shot, Olympus America, Center Valley, PA), Franseen tip (Acquire, Boston Scientific Corporation, Natick, MA) and fork-tip (SharkCore, Medtronic Corporation/Covidien, Newton, MA) needles...

Study Design

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 130 participants
Allocation: Randomized
Intervention Model: Single Group Assignment

Intervention Model Description: This is a randomized trial comparing four types of FNB needles and three sampling techniques. Patients will be randomized to one of the four different FNB needles...

Masking: Triple (Participant, Care Provider, Outcomes Assessor)
Masking Description: The patients, pathologists assessing the biopsy specimens and the research staff responsible for follow-up will be blinded to the FNB needle type utilized...

Primary Purpose: Diagnostic
Official Title: Randomized Trial Comparing Fine Needle Biopsy Needles and Different Techniques for Endoscopic-guided Fine Needle Biopsy of Solid Pancreatic Mass Lesions

Actual Study Start Date: September 9, 2019
Actual Primary Completion Date: June 25, 2020
Estimated Study Completion Date: December 2020

Resource links provided by the National Library of Medicine: MedlinePlus related topics: Biopsy, Genetic and Rare Diseases Information Center resources: Pancreatic Cancer, U.S. FDA Resources

Arms and Interventions

Table with 2 columns: Arm, Intervention/treatment. Row 1: Active Comparator: 22 Gauge FNB Needle - ProCore, Diagnostic Test: Solid pancreatic mass lesion biopsy.

Table with 2 columns: Arm, Intervention/treatment. Row 2: Active Comparator: 22 Gauge FNB Needle - Acquire, Diagnostic Test: Solid pancreatic mass lesion biopsy.

Table with 2 columns: Arm, Intervention/treatment. Row 3: Active Comparator: 22 Gauge FNB Needle - SharkCore, Diagnostic Test: Solid pancreatic mass lesion biopsy.

Table with 2 columns: Arm, Intervention/treatment. Row 4: Active Comparator: 22 Gauge FNB needle - EZ Shot 3 Plus, Diagnostic Test: Solid pancreatic mass lesion biopsy.

Outcome Measures

Primary Outcome Measures: 1. Degree of cellularity in biopsy sample [ Time Frame: 3 days ]

EUS-guided the degree of cellularity of the obtained tissue in the biopsy sample between the four FNB needles in patients undergoing complete sampling of pancreatic masses using the three different sampling techniques...

Secondary Outcome Measures: 1. Diagnostic adequacy of the biopsy sample [ Time Frame: 1 day ]

Documentation of the presence of adequate tissue material (pancreatic parenchyma and tumor if applicable) in the biopsy sample.

2. Specimen bloodiness in biopsy sample [ Time Frame: 1 day ]

Measured as the area of bloodiness in the biopsy sample, with calculation as a percentage in the microscopic field.

3. Presence of crush artefact in biopsy sample [ Time Frame: 1 day ]

Documenting the presence or absence of crush artefact in the biopsy sample. If present, it is measured as the area of artefact in biopsy sample, with calculation as a percentage in relation to the total sample area.

4. Technical failure [ Time Frame: 1 day ]

Measured as the inability to successfully perform the fine needle biopsy using the assigned needle, due to any needle dysfunction.

5. Adverse events [ Time Frame: 7 days, 30 days, and 6 months ]

The subject will be asked to report and medical records will be reviewed for any adverse events related to the procedure or the underlying disease.

6. Diagnostic operating characteristics [ Time Frame: 6 months ]

Compare the diagnostic operating characteristics of the biopsy sample and detection of neoplasia (defined as sensitivity, specificity, negative predictive value, positive predictive value and accuracy) between the four FNB needles in patients undergoing EUS-guided sampling of pancreatic masses using the three different sampling techniques

Eligibility Criteria

Information from the National Library of Medicine: Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study.

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria: 1. All patients referred for EUS-guided tissue acquisition of suspected or confirmed solid pancreatic mass lesions visualized on any radiological imaging

2. Able and willing to provide written or verbal consent

3. ≥ 18 years old

4. Able to undergo conscious sedation for EUS procedure

Exclusion Criteria: 1. <18 years old

2. Unable to obtain informed consent from the patient

3. Medically unfit for sedation

4. Pregnant patients

5. No pancreatic mass lesions visualized on EUS

6. Irreversible coagulopathy as determined by platelet count < 50,000/microL or International Normalized Ratio (INR) > 1.5

7. Unable to stop anti-platelet agents prior to the procedure

Contacts and Locations

Information from the National Library of Medicine: To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT04085055

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Sponsors and Collaborators: AdventHealth

Investigators: Principal Investigator: Shyam Varadarajulu, MD AdventHealth

More Information

Publications: Ngamruengphong S, Li F, Zhou Y, Chak A, Cooper GS, Das A. EUS and survival in patients with pancreatic cancer: a population-based study. Gastrointest Endosc. 2010 Jul;72(1):78-83, 83.e1-2. doi: 10.1016/j.gie.2010.01.072.

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Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: Yes
Product Manufactured in and Exported from the U.S.: Yes

Keywords provided by AdventHealth: pancreatic mass, pancreatic solid mass, pancreatic lesion

Additional relevant MeSH terms: Pancreatic Neoplasms, Digestive System Neoplasms, Neoplasms by Site, Neoplasms, Endocrine Gland Neoplasms, Digestive System Diseases, Pancreatic Diseases, Endocrine System Diseases