Prevalence of Pancreatic Steatosis in Pancreatic Cystic Neoplasms and Pancreatic Adenocarcinoma (SPACE)

Unique Protocol ID: 346833

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Study protocol

Several pancreatic neoplastic cystic lesions, such as IPMN, cystic neuroendocrine tumors (NET) and mucinous neoplasms, present a carcinogenetic risk, though it is yet unknown if this risk is increased in patients with pancreatic steatosis.

The primary objective of the study is to determine de prevalence of pancreatic steatosis in pancreatic neoplastic cysts and if pancreatic steatosis is increased in those lesions that pose a carcinogenetic risk. The secondary objective is to evaluate the prevalence of pancreatic steatosis in pancreatic adenocarcinoma.

Inclusion Criteria:

- Age 18 or older
- Patients with at least 1 pancreatic cystic lesion based on CT and EUS features, with a cyst size ≥ 5mm; or healthy subjects or PDAC (confirmed by histopathological exam).

Exclusion Criteria:

- No evidence of written informed consent
- Patients with contraindications for endoscopy due to comorbidities
- Metal stent in HPB region at time of baseline CT-imaging (vascular, luminal and biliary)
- Acute pancreatitis at baseline imaging
- Pancreatic surgery at baseline imaging in our department
- Splenectomy
- Patients with significant alcohol consumption, defined as alcohol intake of over 20 g daily (140 g weekly) for men and 10 g daily (70 g weekly) for women

Statistical Analysis Plan

Statistical analysis will be conducted using Microsoft Office Professional Plus 2016 Excel and IBM SPSS Statistics 29.0 software. Categorical variables are presented as absolute values and frequencies with percentages. For quantitative variables, means and standard deviations will be used when data followed a normal distribution; otherwise, medians and interval values will be reported. The Mann-Whitney test will be applied to analyze non-normally distributed continuous variables, while the Kruskal-Wallis test will be employed to assess distribution differences across three categories. Statistical significance is defined as a p-value less than 0.05.

Informed consent form

Patient name:_____.

INFORMED CONSENT TO PARTICIPATE IN CLINICAL STUDY

TITLE: Pancreatic Steatosis – an Independent Risk Factor for Pancreatic Tumors

INVESTIGATORS: Dr. Cătălina Vlăduț

What is the pancreas?
The pancreas is an accessory endocrine and exocrine gland of the digestive tract, located in the abdomen, just behind the stomach and duodenum.

What is a pancreatic tumor and what should be done?
A pancreatic tumor can be "benign" (for example, due to inflammation of the pancreas called "chronic pancreatitis") or, unfortunately, "malignant," meaning "pancreatic cancer." Once the type of tumor is determined, appropriate treatment will be recommended. Additionally, the tumor may be solid or cystic. Since the nature of the tumor is currently unknown, an endoscopic biopsy has been recommended.

How will the procedure proceed?
Under anesthesia, a special endoscope (a flexible tube with a camera at the end) will be introduced through the mouth into the esophagus, then into the stomach and duodenum. This special endoscope has a small ultrasound probe at its tip, allowing visualization of your tumor located behind the stomach or duodenum. Using the ultrasound, the tumor will be precisely located, and a very fine needle will be inserted into it to aspirate cells. The tumor will be punctured several times to collect as many cells as possible, which will then be examined under a microscope for an accurate diagnosis.

What is the purpose of this clinical study?
The possibility of diagnosing via endoscopic ultrasound and collecting a histopathological sample during this procedure brings us closer to a diagnosis. Furthermore, analyzing this sample and identifying gene expression provides additional useful information, with important implications for future targeted cancer therapies. The goal of this clinical study is to create a data registry including patients with pancreatic cysts to contribute to high-quality large-scale clinical studies aimed at predicting early diagnostic markers for pancreatic cancer. This will be possible through blood samples and tissue collected via fine-needle aspiration during the endoscopic ultrasound.

Who can participate in this clinical study?
Patients eligible to participate must be over 18 years old, have an imaging-diagnosed pancreatic cystic tumor, and have undergone a CT scan evaluation.

What procedures will be conducted for research purposes?
All participants will complete a questionnaire regarding their health status. This questionnaire may be electronic or paper-based and will be transferred to a database via the internet to ensure confidentiality. Completing the questionnaire will take approximately 10 minutes.

What are the possible benefits of participating in this study?
You will not directly benefit from participating in this research study. However, identifying microRNA expression in pancreatic tumors may assist future studies and help develop new treatments that could benefit future patients.

If I agree to participate, will I be informed about new risks that may arise during the study?
You have the right to be informed about the overall results of the study. You will be updated on new findings during the research that may influence your decision to continue participating. General information will be provided upon request.

Will I or my insurance be charged for any procedures during the study?
No procedures conducted as part of the study will be billed to you or your insurance, as they are part of routine medical care. The hospital will be billed as usual for any routine examinations.

Will I be paid for participating in this study?
You will not receive compensation for participating in this research study. Your responses may contribute to future discoveries. Currently, no financial benefit is anticipated from potential inventions.

Who will know about my participation in this study?
All personal information regarding your involvement in the study will remain confidential and will only be known to the principal investigator and their collaborators.

Is my participation voluntary?
Your participation in this research study is entirely voluntary. You are not obligated to join, and you may withdraw at any time without any consequences. You can also request the immediate destruction of your documents after written consent. You will receive the same quality of medical care regardless of your decision.

Your doctor may be part of the research team and will be concerned about both your well-being and the quality of the research project. Before joining or at any point during the study, you may seek a second medical opinion from a doctor who is not involved in the study. You are not required to participate in any study offered by a physician.

INFORMED CONSENT - FIRM ACCEPTANCE FORM Patient identification number:

The undersigned Mrs./Ms./Mr. (please strike out unnecessary options) (name, surname)..... freely and voluntarily agrees to participate in the biomedical study entitled: Pancreatic Steatosis – an Independent Risk Factor for Pancreatic Tumors, with the principal investigator Dr. (name, surname) .....

I declare that:

- The doctor who informed me and answered all my questions specified that my participation is voluntary and that I can exercise my right to withdraw from the study at any time.
- I understand that I can ask questions about any aspect of the study during its course, and the investigators listed on the first page of this informed consent will answer them. Any questions regarding my rights as a participant in the research study will be addressed by the coordinating physician.
- I authorize genetic studies to be performed on the tissues collected during the fine-needle aspiration as part of the endoscopic ultrasound, as well as on other biological materials (blood).
- I have benefited from a medical consultation before participating in this study, and the results were communicated to me.
- I understand that I can withdraw my consent to participate in this study at any time, for any reason, without any liability, provided I inform the doctor responsible for my participation. Terminating my participation will not affect my relationship with the doctor.
- I am aware that I have the right to request, through my doctor, access to the overall study results when they become available.
- I have not received any remuneration, of any kind, direct or indirect, in exchange for my acceptance or consent to participate in the study.

By signing this informed consent, I agree to participate in this study. I will receive a copy of the informed consent.

....

Participant's Name Date

.....

Participant's Signature

Adults (over 18 years) with impaired cognitive functions who cannot provide informed consent ..... (patient's name). The above-mentioned patient cannot provide informed consent for participation in the research study.

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Representative's Name	Relationship to the Patient
.....	.....
Legal Representative's Signature	Date