Quality registration of EUS-guided tissue acquisition of solid pancreatic lesions

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON26365

Source NTR

Brief title

TBA

Health condition

Pancreatic cancer, IPMN, NET of the pancreas

Sponsors and support

Primary sponsor: QUEST

Source(s) of monetary or material Support: Reinier de graaf Gasthuis

Intervention

Outcome measures

Primary outcome

Rate of adequate sample and diagnostic yield of malignancy

Secondary outcome

Sensitivity for malignancy

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Study description

Background summary

The ASGE described three key performance indicators for EUS-guided tissue acquisition of solid pancreatic lesions. For this study we collect data on EUS-guided FNA/FNB to register quality and yield, and to compare the results to the key performance indicators described in literature. Eventually we provide learning curves for the region, per hospital and per physician, for 2 of the 3 performance indicators. We use the learning curves to evaluate changes in tissue acquisition (other needle, new endosonographer etc) or tissue processing (other medium, liquid based cytology or smears, new pathologist, etc) and we use it as a feedback tool to improve performance. During the three annual meetings the results are discussed in our research group QUEST. This already has led to an improvement of all three performance indicators as discribed in a previous article (PMID 31198843). Another aim of this study is to fins out if procedural factors like use of suction, different types and diameters of needles, number of passes, type of tissue processing, etc influences the yield and outcome of EUS-guided tissue acquisition.

Study objective

Monitoring quality and yield and giving feedback on performance will increase the quality and yield.

Study design

2018, 2020, 2022

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

EUS-guided tissue acquisition of solid pancreatic lesion suspected for malignancy, patient >18 years old

Exclusion criteria

Patient <18 years old, no informed consent

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 01-01-2015

Enrollment: 400

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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Date: 29-04-2021

Application type: First submission

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

NTR-new NL9470

Other METC erasmus MC: MEC-2018-1656

Study results