The value of a molecular diagnostic tool in patients with suspect pancreatic cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23289

Source
NTR

Brief title
NGS study

Health condition

Pancreatic Cancer
Periampullary Cancer
Pancreas kanker
Periampullaire kanker

Sponsors and support

Primary sponsor: Leiden University Medical Center
Department of Surgery and department of Pathology
Source(s) of monetary or material Support: This work was supported by the Bas Mulder Award (grant UL2015-7665) from the Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of NGS

Secondary outcome

- Contribution of NGS to the diagnostic process.

- Percentage of change of treatment type

- Sensitivity and specificity

Study description

Background summary

Determination of the added value of Targeted Next-Generation Sequencing in the diagnostic process of patients with a suspect lesion in or around the pancreas, whose morphological assessment of the preoperative cytology sample is benign or inconclusive.

Study objective

Targeted Next Generation Sequencing (NGS) can distinguish benign pancreatic diseases, such as pancreatitis, from pancreatic malignancies during the diagnostic proces of patients with an uncertain diagnosis and treatment plan.

Study design

After patient inclusion is complete

Intervention

The cytology material, obtained during fine-needle aspiration or brush, is analyzed with NGS, the molecular findings are integrated during the diagnostic process.

Contacts

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Eligibility criteria

Inclusion criteria

• Patient with suspect pancreatic or periampullary lesion (papil; duodenum; distal bile duct); or patients with suspect cysts

• Sufficient radiological images; assessed by specialized radiologist

• Sufficient clinical assessment; including bilirubine levels and CA19.9 levels

• Cytology sample available for pathological assessment; either obtained with FNA, brush or punction from cystic wall

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	57
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-01-2018
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	NL6819
NTR-old	NTR7006
Other	Protocolnummer METC : P17.213

Study results

Summary results

Prior publication:

https://www.ncbi.nlm.nih.gov/pubmed/28775172