Pancreatic Cyst Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55677

Source
ToetsingOnline

Brief title
Pancreatic Cyst Study

Condition

- Other condition

Synonym
Pancreatic cyst

Health condition

benigne, premaligne en maligne neoplastische pancreascysten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cyst fluid analysis, DNA mutational analysis, Malignant transformation, Pancreatic Cysts

Outcome measures

Primary outcome

- To determine the proportion of patients with malignancy in operable

pancreatic cysts.

- To determine the sensitivity, specificity, and overall accuracy of imaging

(CT, MRI and EUS) in patients with pancreatic cysts.

- To determine the factors associated with malignancy in pancreatic cyst using

a multivariate model including clinical, radiologic, and molecular markers.

- To develop and prospectively validate a panel of molecular markers to

differentiate benign pancreatic cysts from those with malignant potential using

surgical pathology as the gold standard.

Secondary outcome

- To determine the proportion of IPMN based on molecular markers.

- To determine of the natural history of IPMN.

- To collect tissue samples (cyst fluid and blood) for research on molecular

markers in pancreatic cysts.

Study description

Background summary

Pancreatic cysts are increasingly recognized as incidental lesions due to the widespread use of cross-sectional imaging techniques such as CT and MRI. Twenty percent of all pancreatic cysts are non-inflammatory cystic neoplasms,

many of which are mucinous, and therefore have a significant potential for malignant transformation. The primary challenge facing clinicians is the inability of current standard diagnostic tests to accurately and reliably discriminate neoplastic from non-neoplastic, and benign from malignant cysts, particularly in patients without symptoms. Asymptomatic patients with pancreatic cysts may be misdiagnosed and treated with unnecessary surgical resection. The International Association of Pancreatology (IAP) has published guidelines on the management of the two main types of mucinous cystic lesions: intraductal papillary mucinous neoplasms (IPMNs) and mucinous cystic neoplasms (MCNs) (Tanaka et al. 2012). Although these guidelines emphasize the frequency of surveillance and outline the indications for resection, they have not yet been validated, and they presume the diagnosis of a mucinous neoplastic cyst has been confirmed prior to surgery. It is unlikely that guidelines that only use clinical and imaging will be able to accurately differentiate benign cysts from those that are pre-malignant or currently harbor cancer. Hence, there is a critical need for a diagnostic model that more accurately diagnoses neoplastic mucinous and malignant pancreatic cysts.

Study objective

The general aim is to propose and prospectively validate a diagnostic approach and model for prediction of mucinous versus non-mucinous, and malignant versus non-malignant, pancreatic cysts using a combination of clinical, radiologic, and biomarker characteristics.

Study design

Prospective, multi-center study

Study burden and risks

There are no additional risks above those related to standard clinical care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Adult patients age 18 years and older.
* Referred for assessment of a pancreatic cyst.

Exclusion criteria

* Medically ill patients with ASA class 4 or greater.
* Inability to provide informed consent.
* Pregnancy or lactation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-05-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02110498
CCMO	NL49988.018.14