# Differential diagnosis and follow-up of cystic neoplasms of the pancreas: advanced radiologic imaging and cyst fluid analysis

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To identify new means to improve the differential diagnosis of pancreatic cystic lesions to guide patient management.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

# **Summary**

### ID

NL-OMON30334

**Source** ToetsingOnline

Brief title Pancreatic cysts study

### Condition

• Gastrointestinal stenosis and obstruction

**Synonym** cystic tumors of the pancreas, neoplastic cysts

**Research involving** Human

### **Sponsors and support**

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

#### Intervention

Keyword: Differential diagnosis, Endosonography, Pancreatic cystic lesion, Proteomics

#### **Outcome measures**

#### **Primary outcome**

The primary aims are to identify new means to improve the differential diagnosis of pancreatic cystic lesions to guide patient management and to assess the biological behaviour of the pancreatic cystic lesions.

#### Secondary outcome

To describe a large single-centre experience with pancreatic cystic lesions, including presenting signs and symptoms and methods of diagnosis.

To assess the development and natural behaviour of pancreatic cysts according to a predefined follow-up scheme/ regimen.

To identify new biomarkers of pancreatic cystic neoplasms using proteomics technology and assess their feasibility and reliability compared to well-known tumor markers and enzymes for pathological diagnosis in patients with a pancreatic cystic lesion.

To make recommendations for the accurate diagnosis and optimal treatment of patients with all types of pancreatic cystic lesions.

# **Study description**

#### **Background summary**

An increasing number of asymptomatic individuals with pancreatic cystic lesions are being identified because of a more frequent use of sophisticated abdominal imaging techniques. Cystic lesions of the pancreas comprise of a heterogeneous group of diagnostic entities, some of which are (virtually) benign such as inflammatory pseudocyst or serous cystadenoma and, when asymptomatic, do not require surgical resection. Others have a malignant potential (mucinous cystic neoplasms or intraductal papillary mucinous neoplasms (IPMN)) and in these cases surgical resection is indicated. Because of pre-operative difficulties in characterizing the nature of pancreatic cystic lesions and a cautious management strategy based on the policy not to withhold a patient from a rightly indicated resection (pre-malignant and malignant lesions), many asymptomatic people with truly benign lesions undergo surgery as a consequence. Therefore, adequate distinction between the various types of pancreatic cystic lesions should allow for a better selection of patients to prevent patients with truly benign lesions to be exposed to unnecessary surgery with associated morbidity and mortality. Techniques that potentially could be of value in the differentiation include radiologic imaging techniques (MR, viscosity/density measurements, endosonography) and the use of new biomarkers including proteomics technology.

#### **Study objective**

To identify new means to improve the differential diagnosis of pancreatic cystic lesions to guide patient management.

#### Study design

This prospective protocol will incorporate various investigational techniques such as MR scan, EUS and EUS-FNA (fluid sampling including brush cytology). The value of the various imaging techniques will assessed by linking imaging features to the clinical outcome (surgery, follow-up). EUS will be the main device in order to assess cystic changes and perform follow-up. Additionally, MR will be used to measure the viscosity/density index of the lesions. Newly developed EUS brush cytology devices will be used to obtain cytology from the inner wall of the cyst to be analysed by means of conventional cytology and EUS-FNA will be employed to sample cyst fluid for biochemical and biomarker assessment including the use of proteomics.

#### Study burden and risks

Main burden of participation is the initially 6-monthly follow-up in which the subject undergoes repeated endosonographic investigations and blood sampling, which both are considered low-risk interventions. Major benefits might occur when a subject doesn\*t have to undergo extensive pancreatic surgery, when this

turns to be unnecessary.

# 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**

Cystic lesion on cross-sectional imaging (percutaneous ultrasound and/or CT scan and/or MR scan) Suspicion of a pancreatic neoplasm

### **Exclusion criteria**

Acute phase of an acute pancreatitis

PT-INR>1.5, PTT>50, trombocytes<50.000 Synchronic malign neoplasm in stomach / colon / rectum / lung / breast / liver

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	150
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Application type:	First submission
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

ССМО

**ID** NL14139.018.06