A prospective evaluation of pancreatic cyst surveillance, based on the consensus statement, formulated by the European study group on cystic tumours of the pancreas

Published: 10-03-2014
Last updated: 25-09-2024

First, to establish the yield of the currently propagated pancreatic cyst surveillance program, and second, to identify possible alternative surveillance strategies, which might be more (cost) effective.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON55977

Source
ToetsingOnline

Brief title
Pancreatic cyst follow-up, an international collaboration/ PACYFIC study

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
cystic tumor of the pancreas, Pancreatic cyst

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Follow-up, Pancreatic cyst, Surveillance

Outcome measures

Primary outcome

Primary endpoints are:

1. Number of cysts reaching an indication for resection.

2. Number of patients, diagnosed with a malignant cyst (either high-grade dysplasia or carcinoma).

Secondary outcome

Secondary endpoints are to evaluate:

1. The course of patients with an indication for cyst resection (surgery, outcome, and recurrence).

2. Cyst evolution, in terms of development of symptoms, cyst growth, nodules, and secondary duct dilation.

3. The perceived burden of surveillance for participating subjects.

4. Potential risk factors for malignancy.

and

5. To build a micro-simulation screening analysis (MISCAN) model, based on the outcome data of this study, in order to determine the optimal surveillance strategy for pancreatic cysts.

Study description

Background summary

Asymptomatic pancreatic cysts are a common finding in this time of elaborate imaging. The malignant potential of these cysts is probably small, but data regarding risks are not available. Generally, an intensive surveillance strategy is chosen, driven out of fear to miss one of the most deadly cancers, and based on international recommendations. This strategy may be justified for some individuals, to timely detect malignant progression, but the majority of cysts will never progress. Consequently, most patients are undergoing lifelong redundant (and costly) investigations.

Study objective

First, to establish the yield of the currently propagated pancreatic cyst surveillance program, and second, to identify possible alternative surveillance strategies, which might be more (cost) effective.

Study design

An international multicenter observational cohort study that will run for 15 years. The first analysis will take place in 2018. Results will be available in 2020.

Study burden and risks

There will be no risk for patients participating in this study. The follow-up schedule is in accordance with common practice and recently published treatment recommendations. The burden for participating patients will be to fill out a questionnaire after each follow-up visit. In addition, two to three extra blood samples will be obtained, during the vena-puncture procedure that is part of the follow-up schedule. At last, pancreatic juice will be collected in patients with worrisome features after injection of secretine, which does not harbor any significant risks, yet prolongs procedure time with 5-10 minutes.
A part of the participants with a low-risk cyst will be participating in a one-time focus group or interview. All the participants with a low-risk cyst will get a one-time additional questionnaire.
A potential benefit of study participation will be a better compliance to the surveillance program.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Individuals with a pancreatic cyst (either newly or previously diagnosed)
• Cyst surveillance is warranted, according to the treating physician
• Age >18
• Informed consent

Exclusion criteria

• History of chronic pancreatitis
• Suspected pseudocyst
• Suspected serous cystadenoma
• Von Hippel-Lindau disease

• Limited life expectancy (< 2 years)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2015
Enrollment:	2500
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-07-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	09-11-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2023
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-10-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-07-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-09-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL45556.078.13