Individuals at high-risk for developing pancreatic cancer: surveillance by endosonography and magnetic resonance imaging: FAMILIAL PANCREATIC CANCER SURVEILLANCE STUDY

Published: 16-07-2007
Last updated: 08-05-2024

To prospectively evaluate the feasibility and effectiveness of surveillance of individuals at high-risk for developing pancreatic cancer, in order to detect non-symptomatic (early) neoplastic lesions at a stage when curative resection is still...

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON31426

Source
ToetsingOnline

Brief title
FAMILIAL PANCREATIC CANCER SURVEILLANCE STUDY

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic neoplasia

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: High-risk, Imaging techniques, Pancreatic carcinoma, Surveillance

Outcome measures

Primary outcome

Frequency of pancreatic cancer or precursor lesions.

Secondary outcome

The false positive rate of surveillance strategy in FPC after resection surgery

Interobserver variability of endosonography in the surveillance of FPC

Interobserver variability of MRI in the surveillance of FPC

Cost-effectiveness of different surveillance scenarios in this population of

cancer-prone individuals

Identification of novel biomarkers which accurately detect early pancreatic

neoplasia.

Identification of unknown gene(s) responsible for the hereditary forms of PC

Determination of pancreatic neoplasia prevalence in known hereditary syndromes

in order to improve risk stratification and provide more accurate estimates of

individual cancer risk.

Study description

Background summary

Pancreatic cancer (PC) is among the most fatal human cancers, in part because of late diagnosis and a lack of effective therapies. At the time of diagnosis, most patients have irresectable disease due to local vascular involvement or distant metastases. In such cases the median survival is about 6 months. Thus, for individuals at high risk of developing PC there is an urgent need for effective surveillance methods. Aside from cigarette smoking, family history is the only other well-established epidemiological risk factor in PC. About 10% of cases are believed to be caused by inherited genetic factors and in some instances the risk of developing pancreatic cancer can approach 50%. The ability to surveil high-risk patients would significantly enhance the potential for early diagnosis, thereby identifying the disease at an potentially curable stage.

Study objective

To prospectively evaluate the feasibility and effectiveness of surveillance of individuals at high-risk for developing pancreatic cancer, in order to detect non-symptomatic (early) neoplastic lesions at a stage when curative resection is still possible.

Study design

Yearly surveillance in this prospective protocol will be performed by EUS and MRI. In case of abnormalities additional investigations will be performed including EUS-FNA (tissue sampling). Blood samples and feces are collected to search for potential tumormarkers in the screening of high-risk individuals.

Study burden and risks

Main burden of participation is a yearly follow-up investigational program consisting of an endosonographic investigation, MR-scanning, blood sampling and feces collection all of which are considered low-risk interventions. Major benefits might occur when a precursor lesion or early PC is detected while it

is still resectable.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

PC prone hereditary syndromes with a cumulative lifetime risk >10% on PC, or
PC prone hereditary syndromes with a unknown cumulative lifetime risk, or <10% for PC, with a familial aggregation of PC (* 2 first-degree relatives with a histologically confirmed PC, or * 3 relatives of any degree with a histologically confirmed PC, one of whom must have been a first-degree relative, or * 2 relatives of any degree, one of whom was at least * 50 years at the time of diagnosis, with a histologically confirmed PC), or
Familial pancreatic cancer (* 2 first-degree relatives with a histologically confirmed PC, or * 3 relatives of any degree with a histologically confirmed PC, one of whom must have been a first-degree relative, or * 2 relatives of any degree, one of whom was at least * 50 years at

the time of diagnosis, with a histologically confirmed PC), apparently unrelated to any currently recognized hereditary syndrome

Exclusion criteria

Clinical evidence of PC and / or PC in the medical history,
Medical comorbidities or coagulopathy that contraindicate endoscopy,
Medical comorbidities or coagulopathy that contraindicate pancreatic surgery,
Karnofsky performance score < 60

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):	01-03-2007
Enrollment:	150
Type:	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	ID
CCMO	NL16302.018.07