Tumor profiling in pancreatic carcinoma, a multidisciplinary initiative

Published: 03-11-2011
Last updated: 29-04-2024

Primary Objective(s): In this study we try to unravel the behavior of stem cells in relation to their (stromal) niche, genetic mutations, altered RNA expression and expression of tumor markers in serum for better prognostication of pancreatic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35953

Source
ToetsingOnline

Brief title
Pancreas bio bank project

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
pancreatic cancer, pancreatic carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bio bank, genetics, pancreatic carcinoma, stem cel

Outcome measures

Primary outcome

The expression of stem cell markers in cell cultures and xenograft models, serum protein markers, and DNA/RNA profiles, will be correlated to clinicopathological characteristics like survival and TNM classification.

Secondary outcome

Amount of viable tumor cells in biopsies taken at the OR/Pathology (quality comparison).

Optimal procedures for processing of the tissues (we follow standard operating procedures in the laboratories).

Study description

Background summary

Pancreatic adenocarcinoma is a malignancy with a poor prognosis. At this moment resection is the only curative option, and even this only yields a 5 year survival of less than 10 percent.
Furthermore, due to the nature of the tumor and the intense stromal reaction around the tumor cells, pancreatic adenocarcinoma is relatively insensitive to current chemotherapeutics. More insight into both the interaction of tumor (stem)cells with their niche through altered signalling and selfrenewal pathways, as well as the genetic mutations that underlie these entities can provide a rationale for novel therapies. Correlating these tumor biology parameters to clinicopathological outcome can identify patient subgroups with a different prognosis and aid in the selection of patients who are eligible for curative surgical therapy. At this moment we are not routinely collecting material for these studies. By establishing a pancreas bio bank we want to create a valuable source of tumor material stored and processed following high quality standardized procedures following current guidelines.

Study objective

Primary Objective(s): In this study we try to unravel the behavior of stem cells in relation to their (stromal) niche, genetic mutations, altered RNA expression and expression of tumor markers in serum for better prognostication of pancreatic carcinoma. For this we will include patients with a suspicion of a pancreatic carcinoma undergoing explorative laparotomy with curative intent, or patients who undergo biopsies for palliative treatment and assess tumor biology in relation to clinicopathological parameters.

Secondary Objective: To create the optimal logistic procedures to provide a standardized collection of all patient tissue biopsies and blood samples needed for our research in both resectable and (a priori or during exploration) irresectable patients, and to increase the biological integrity of the pancreatic tissue by providing a dedicated logistic network between the departments of Surgery, Pathology, Medical Oncology and the Center for Experimental Molecular Medicine in the Academic Medical Center.

Study design

Creating the pancreas bio bank is a prospective process. Observational laboratory studies (with DNA/RNA isolation, microarrays, cell culturing and xenografting) will be performed with primary tumor specimens, metastases and blood samples stored and processed in the bio bank.

Study burden and risks

For the patient there are no substantial burdens or risks associated with participation in the study, since routine diagnostic and therapeutic procedures are followed. The study will probably benefit future patients through an increase in understanding of pancreatic tumorbiology.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9

1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Suspicion of potentially resectable and irresectable pancreatic malignancy on preoperative imaging

Exclusion criteria

Not able to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-09-2011
Enrollment:	200
Type:	Actual

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	NL36420.018.11