The Diagnostic and Predictive Value of Different Biomarkers in Pancreatic Juice and blood in Patients with Pancreatic Cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25284

Source
NTR

Brief title
KRASPanc

Health condition

Pancreatic cancer

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: investigator initiated.

Intervention

Outcome measures

Primary outcome

Ct-DNA levels in pancreatic juice and serum in relation to (progression-free) survival.

Secondary outcome

Ct-DNA levels in pancreatic juice and serum

CINdex in pancreatic juice and serum

The cellular composition of pancreatic juice (Number of cancer cells, Clonality of the cancer cells, Intracellular (single-cell) mutations, capability to grow organoids)

Molecular composition of pancreatic juice (Levels of pro- and anti-inflammatory molecules, inhibitory and activating immune cells, molecules related to fibrosis)

(Progression free) survival (assessed after 12 and 18 months)

Tumour size

Presence of metastases

Study description

Background summary

The incidence of pancreatic cancer (PC) in the Netherlands is low, yet the prognosis is dismal. In 2030, PC is even expected to be the number one cause of cancer related death, worldwide. At present, PC diagnosis is based on imaging, yet the development of biomarkers is needed, not only to enable timely detection, but also to allow personalised care and early prediction of treatment response. Individual biomarkers seem to have a limited predictive value. A broad approach is needed, investigating different molecular markers in different biomaterials (serum and pancreatic juice) to develop a combination of tests that will improve PC survival. We expect to detect cellular and extra-cellular components of the tumour in pancreatic juice and serum (ct-DNA, cytokines, fibrotic mediators), serving as promising targets for biomarker detection.

Study objective

We hypothesize to find an association between these ct-DNA levels in pancreatic juice and blood and (progression-free) survival.

Study design

Pancreatic juice and serum collections will be performed during EUS. Further disease and survival characteristics will be collected up to 2 year after inclusion.

Intervention

No interventions

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

All patients with (suspected) pancreatic cancer that undergo an EUS either as part of a diagnostic process or for fiducial placement prior to treatment.

Exclusion criteria

A potential subject that is younger than 18 years old will be excluded from participation in this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2018
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54838
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7383
NTR-old	NTR7591
CCMO	NL64724.078.18
OMON	NL-OMON54838

Study results