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

Published: 23-10-2018
Last updated: 19-03-2025

To establish the diagnostic and predictive value of different biomarkers in patients with pancreatic cancer by the investigation of:- Mutated ct-DNA levels in pancreatic juice and blood.- Chromosomal instability in pancreatic juice and blood.- Pro-...

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

Summary

ID

NL-OMON54838

Source
ToetsingOnline

Brief title
KRAS mutation as a diagnostic biomarker.

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreascarcinoma., Pancreatic cancer

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: Biomarker., KRAS mutation., pancreatic cancer.

Outcome measures

Primary outcome

Main study parameter: CtDNA levels in pancreatic juice and blood in relation to (progression-free) survival.

Secondary outcome

Secondary study parameters (in patients undergoing EUS or ERCP for (suspected) PC)

- CtDNA levels in pancreatic juice and blood.

- CINdex in pancreatic juice and blood.

- The cellular composition of pancreatic juice: number of cancer cells, clonality of the cancer cells, intracellular (single-cell) mutations (e.g. KRAS, CDKN2A, SMAD-4, TP53), the capability to grow organoids.

- Molecular composition of pancreatic juice and blood: levels of pro- and anti-inflammatory molecules, levels and function of inhibitory and activating immune cells, levels of molecules related to fibrosis.

- (Progression free) survival (assessed after 12 and 18 months) based on morphology on MRI and EUS.

- 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 personalized 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 (pancreatic juice and blood) to develop a combination of tests that will improve PC survival. We expect to detect cellular and extra-cellular (ct-DNA, cytokines, fibrotic mediators) components of the tumour in pancreatic juice and blood, serving as promising targets for biomarker detection.

Study objective

To establish the diagnostic and predictive value of different biomarkers in patients with pancreatic cancer by the investigation of:
- Mutated ct-DNA levels in pancreatic juice and blood.
- Chromosomal instability in pancreatic juice and blood.
- Pro- and anti-inflammatory molecules in pancreatic juice, tumour specimens and blood.
- Fibrotic mediators in pancreatic juice and tumour specimens.

Secondary objectives:
- To evaluate the cellular compartment of pancreatic juice from PC patients and the ability to grow organoids from it.

Study design

This is a single-centre prospective study, performed in 200 patients undergoing EUS or ERCP for (suspected) PC. Molecular and cellular compartments of pancreatic juice, blood-derived materials (serum and plasma) and tumour tissue will be related to cancer presence, tumour size, the presence of metastases and survival. Additionally, patients with PC will be compared with patients undergoing EUS or ERCP for (suspected) pancreatitis, neuro-endocrine tumour or a non-pancreatic reason (e.g. choledocholithiasis). Furthermore, organoids will be grown from cancer-cells extracted from pancreatic juice and tissue.

*

Study burden and risks

The burden will consist of one blood collection from the drip per endoscopic ultrasound or ERCP. In addition, secretin will be administered intravenously during the procedure, to promote wash-out of pancreatic juice per endoscopic ultrasound or ERCP.

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

Patients with (suspected) pancreatic tumour, chronic pancreatitis and healthy controls (non-pancreatic non-healthy) that undergo an endoscopic ultrasound or ERCP.

The latter group is defined as all individuals undergoing endoscopic ultrasound or ERCP for a non-pancreatic indication (e.g. choledocholithiasis), individuals with a personal history with pancreatic disease (including pancreatic cysts, pancreatitis or any other pancreas-related disease, post-surgery) or autoimmune disease will not be included in this group. In addition, patients with a history of malignancy could only be included if they have been treated curatively >5 years ago.

Exclusion criteria

Age < 18 years.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2018
Enrollment:	530
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	18-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-11-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-05-2023
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

ID: 25284
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64724.078.18
OMON	NL-OMON25284