Immune monitoring in pancreatic cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27380

Source
NTR

Health condition

pancreatic cancer
alvleesklierkanker

Sponsors and support

Primary sponsor: Foundation for Liver and Gastrointestinal Research (SLO)
Source(s) of monetary or material Support: Foundation for Liver and Gastrointestinal Research (SLO)

Intervention

Outcome measures

Primary outcome

•To determine the baseline immune signature in pancreatic cancer patients.

Secondary outcome

•To investigate whether the immune profile found in the PB reflects the local immune signature of the pancreatic tumor.

•To determine the effect of standard of care treatment (neoadjuvant CRTx, adjuvant

chemotherapy or palliative chemotherapy) on the expression of co-inhibitory molecules and their ligands on TIL and PB lymphocytes.

Study description

Background summary

Patients diagnosed with pancreatic cancer have a poor survival. There is a strong need for new therapeutic approaches. The presence of pancreatic cancer is known to affect the functionality of the immune system and furthermore chemotherapy (CTx) and (chemo)radiotherapy (CRTx) can subvert immunosuppressive mechanisms, or elicit immune responses by immunogenic cell death of cancer cells. In depth analysis of the systemic (blood) and local (tumor tissue) immune parameters in patients with pancreatic cancer and during conventional therapies could reveal new insights in the interplay of these treatment modalities with the immune system and provide a basis/rationale for new (immuno)therapeutic approaches and combination therapies, e.g. including immune checkpoint blockade, adoptive immune therapies, Toll like receptors agonist and interferons in the current standard of care treatments.

Study objective

analysis of the systemic (blood) and local (tumor tissue) immune parameters in patients with pancreatic cancer and during conventional therapies could reveal new insights in the interplay of these treatment modalities with the immune system and provide a basis/rationale for new (immuno)therapeutic approaches and combination therapies.

Study design

In general we will obtain a baseline sample from every patient (e.g. before surgery or before start of treatment) followed by several samples during their treatment course based on start of therapy and follow-up after each cycle of CTx and/or RTx (maximized at 11 timepoint in total).

Intervention

Blood collection

Contacts

Public
's-Gravendijkwal 230

C.H.J. van Eijck
Surgery department Erasmus MC
Rotterdam 3000 CA
The Netherlands
+31 10 703 3854
Scientific
's-Gravendijkwal 230
C.H.J. van Eijck
Surgery department Erasmus MC
Rotterdam 3000 CA
The Netherlands
+31 10 703 3854

Eligibility criteria

Inclusion criteria

•Age ≥ 18 years

•Diagnosed with resectable or borderline resectable pancreatic cancer, locally advanced pancreatic cancer or metastasized pancreatic cancer

•Planned treatment with either of the currently available standard of care treatments for pancreatic cancer (e.g. surgery, gemcitabine, FOLFIRINOX and/or radiotherapy)

•Signed informed consent

Exclusion criteria

•Unable to draw blood for study purposes

•Serious concomitant systemic disorders that would compromise the safety of the patient or his/her ability to complete the study, at the discretion of the investigator.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2016
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-12-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45549
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6173
NTR-old	NTR6320
CCMO	NL59131.078.16
OMON	NL-OMON45549

Study results