Immune monitoring in pancreatic cancer

Published: 19-10-2016
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To determine the local and systemic immune profile, with emphasis on T lymphocytes, in pancreatic cancer patients; and monitor how these immune profiles are affected by treatment for individual patients.

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

Summary

ID

NL-OMON45549

Source
ToetsingOnline

Brief title
Immune monitoring in pancreatic cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic ductal adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek
Source(s) of monetary or material Support: Stichting Overleven met Alvleesklierkanker

Intervention

Keyword: immune monitoring, pancreatic cancer, T cell effector functions

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 monitor the effect of 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 therapy 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 current treatment modalities.

Study objective

To determine the local and systemic immune profile, with emphasis on T lymphocytes, in pancreatic cancer patients; and monitor how these immune profiles are affected by treatment for individual patients.

Study design

Multicenter prospective cohort study

Intervention

Whole blood will be collected from 100 pancreatic cancer patients. A small part of tumor will be stored for analysis from patients who will undergo a resection.

During the course of the study blood will be collected multiple times. The number of blood collections depends on the exact diagnosis:

- resectable and borderline resectabele pancreatic cancer, maximum of 11 collections during a maximum period of 30 weeks
- locally advanced pancreatic cancer, maximum of 5 collections during a maximum period of 40 weeks
- metastatic pancreatic cancer, maximum of 4 collections during a maximum period of 17 weeks

An immune profile will be determined for each timepoint. This will enable us to track changes in the immune system during the whole treatment course of the individual patient. This will make it possible to detect changes related to treatment interventions, e.g. chemotherapy. In the future we could possible adapt treatment guidelines in such a way that we can optimize the function of the immune system during the course of treatment.

Study burden and risks

Intervention

- resectable and borderline resectabele pancreatic cancer, maximum of 10 collections (200 ml whole blood) during a maximum period of 1 year
- locally advanced pancreatic cancer receiving FOLFIRINOX, SBRT and resection, maximum of 10 collections (200 ml whole blood) during a maximum period of 40 weeks
- - locally advanced pancreatic cancer only receiving SBRT, maximum of 5 collections (300 ml whole blood) during a maximum period of 25 weeks
- metastatic pancreatic cancer, maximum of 4 collections (80 ml whole blood) during a maximum period of 17 weeks
- pancreatic cancer patients receiving immunotherapy on a named patient basis (e.g. Ampligen®) or DC therapy, maximum of 4 collections (80 ml whole blood) during a maximum period of 18 weeks
- patienst who have been treated with dendritic ell therapy, maximum of 1 collection (20 ml) after treatment completion.

Risks

There are considered to be no extra risks in participating in this study.

Benefit

We expect that in the future patients diagnosed with pancreatic cancer can benefit from the results of this research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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 currently available standard of care treatments for pancreatic cancer (e.g. surgery, gemcitabine, neoadjuvant chemoradiotherapy, FOLFIRINOX and/or (stereotactic) radiotherapy) or new

treatment options such as, but not limited to, Ampligen® (immunotherapy) or DC therapy.
• 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: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2016
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-01-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-04-2024
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: 27380
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59131.078.16
OMON	NL-OMON27380