Immunogenic Neoantigen Profiling in Pancreatic Cancer - IMPRINT

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To identify and synthesise patient-specific neoantigen peptides from residual material of resected pancreatic cancer tissue, from the organoids established from the resected pancreatic cancer tissue (MEC-2021-0325) and from peripheral blood.

Ethical review	Approved WMO
Status	Pending
Health condition type	Exocrine pancreas conditions
Study type	Observational invasive

Summary

ID

NL-OMON57417

Source
ToetsingOnline

Brief title
IMPRINT

Condition

- Exocrine pancreas conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic ductal adenocarcinoma

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,NeOncoFRax

Intervention

Keyword: neoantigens, pancreatic cancer, peronalised immunotherapy

Outcome measures

Primary outcome

The main study endpoints are identifying patient-specific neoantigens from PDAC tumour material, evaluating the feasibility and efficacy of our peptide production laboratory in synthesising the predicted neoantigens as peptides and testing their in vitro immunogenicity to elicit tumour-specific T cells.

Secondary outcome

Secondary endpoints are to identify patient-specific neoantigens from PDAC organoids and their immunogenicity and to conduct comprehensive oncologic, molecular and immunological analyses, including but not limited to RNA-based immune infiltration analysis, DNA damage repair analysis, single-cell sequencing, TCR sequencing, and spatial biology analysis.

Study description

Background summary

Pancreatic cancer is notorious for its aggressive nature and poor prognosis. Traditional treatment options such as chemotherapy and radiation therapy have limited efficacy. By studying neoantigens, which are patient- and tumour-specific due to somatic mutations, it becomes possible to develop personalised immunotherapies tailored to target these specific antigens. This approach holds promise for improving treatment outcomes by harnessing the immune system of a patient to target and destroy cancer cells selectively.

Study objective

To identify and synthesise patient-specific neoantigen peptides from residual material of resected pancreatic cancer tissue, from the organoids established

from the resected pancreatic cancer tissue (MEC-2021-0325) and from peripheral blood.

Study design

This is a prospective single-centre, translational, proof-of-concept study. The study design consists of one additional blood draw prior to or during routine surgery for pancreatic cancer. In addition, we will collect residual tumour material. The blood as well as DNA and RNA extracted from the residual material of the resected tumour specimen, will be used to identify patient-specific neoantigens. We will collect one additional sample of 60 ml of peripheral blood for each patient.

Study burden and risks

Patients will not have to visit the hospital for additional visits during this study. Signing of Informed Consent will occur after they have been scheduled for routine surgery, preferably on the day of their visit to the anaesthesia department. The only intervention during this study is the collection of additional blood from an existing venous access during standard-of-care surgery. This intervention is associated with very minor discomfort, such as bruising. In addition, residual tissue will be collected with no associated risks or burdens. Overall, the additional burden and risks are negligible.

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

To be eligible to participate in this study, a subject must meet all the following criteria:
• Histological or cytological (Bethesda 5 or 6) confirmed PDAC, as indicated by a definite cytology/histology report.
• Scheduled for surgical removal of the pancreatic tumour.
• Age >= 18 years.
• Provision of written informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Diagnosis of immunodeficiency.
• Received systemic steroid therapy or any other form of immunosuppressive therapy within 14 days before the screening. The following are exceptions to this criterion:
o Intranasal, inhaled, topical steroids, or local steroid injections (e.g., intra-articular injection).
o Systemic corticosteroids.
o Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-04-2025
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL87964.078.24