# Determing the cellular immunophenotype-genotype interactions in pancreatic cancer towards targeted personalized immunotherapies

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Malignant and unspecified neoplasms gastrointestinal NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON45339

**Source**
ToetsingOnline

**Brief title**
Immunophenotype-genotype interactions in pancreatic cancer

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

**Synonym**
pancreatic cancer, Pancreatic Ductal AdenoCarcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W,ISPIC project part of the Horizon 2020 program Marie Sklodowaska Curie Action-Innovative Training Network funded by the European Commission

## Intervention

**Keyword:** Immunophenotype, Pancreatic cancer, Personalized immunotherapies

## Outcome measures

### Primary outcome

The main study endpoint consists in determining which immunophenotype-genotype interactions play a dominant role in the pathogenesis of PDAC and if we can therapeutically target these interactions. We will also be able to correlate the immunophenotyping with overall survival thereby conceptualizing an immunoprofile score.

### Secondary outcome

NA

# Study description

### Background summary

The objective treatment response of patients with advanced staged tumors treated with anti-CTLA4, -PD-1, or *PD-L1 antibodies is very encouraging. Most of the current immunotherapies work at least in part by activating the immune system to target the tumor cells. But without knowing the immune competence of a particular patient, such strategies may fail, or work only in a fraction of patients. To date immunotherapies have not shown much promise for patients with Pancreatic Ductal Adenocarcinoma(PDAC). This observation suggests that a deeper understanding of the phenotype-genotype interactions and genetic heterogeneity is necessary before one can envision personalized immunotherapeutics.

### Study objective

The global aim of this project is to determine the immunophenotype-genotype interactions of PC. The novel insights in the molecular genomic and

immunological profile of the tumor tissue and metastases are expected to help determine the immune activation within PC patients. This approach helps the development of effective immune therapy in PC and in turn could predict whether patients would benefit from targeted personalized immunotherapies.

### Study design

This is a preclinical study with translational focus. The immune Tumor Micro-Environment (TME) of resected pancreatic tumors and associated lymph nodes will be analyzed by mass cytometry and correlated with the analysis of peripheral- and portal vein blood samples of the same patients. Furthermore, Next Generation Sequencing(NGS)-based analysis of tumor genomes and transcriptomes will be performed in order to correlate gene expression and mutation profiles with the immunophenotypes found in the TME.

### Study burden and risks

The burden or risks for patients are minimal as studies will be performed on material derived from regular surgical procedures as well as from blood samples collected through venapuncture. We asked the patient enrolled to give 50mL (5 tubes) of blood before the operation and 50 ml(5 tubes) after the operation whilst still in the hospital. Afterwards the collection of blood samples will be combined with the outpatient clinic appointments, so as to not cause any inconvenience for the patients.

## 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

Pancreatic cancer tissues and immune cells from patients diagnosed with severl types of pancreatic caner planned to undergo explorative surgery with or without resection.

### Exclusion criteria

Severe anemia (Hb<6.0 mmol/L)
Tumors <1 cm

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-11-2017 |
| Enrollment: | 60 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 03-10-2017 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

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| Approved WMO Date: | 06-09-2018 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
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| Approved WMO Date: | 09-04-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

## 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 | NL60888.058.17 |