# **APPART** study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

# **Summary**

### ID

NL-OMON20200

Source NTR

Brief title APPART

#### Health condition

Pancreatic ductal adenocarcinoma (PDAC)

### **Sponsors and support**

**Primary sponsor:** Department of Surgery, Erasmus Medical Center Rotterdam **Source(s) of monetary or material Support:** Support Casper

### Intervention

### **Outcome measures**

#### **Primary outcome**

The level of PDAC-specific oncolytic activity of vermiform appendix derived T lymphocytes

#### Secondary outcome

Identification of

- PDAC specific antigens
- appendix fecal microbiome diversity

- molecular immune landscapes in the vermiform appendix sana from patients with PDAC compared to controls

- differential T-cell and B-cell receptor repertoires in peripheral blood lymphocytes vs lymphocytes from the vermiform appendix, in patients with PDAC.

# **Study description**

#### **Background summary**

Pancreatic ductal adenocarcinoma (PDAC) is notorious for its immune-suppressive tumor microenvironment, low numbers of intratumoral cytotoxic T-cells (CTLs) which are often functionally exhausted and its poor immune checkpoint inhibitor response. Our preclinical studies performed in immune competent PDAC mouse models have shown that gut associated lymphoid tissue (GALT) represents a potential source for pancreatic cancer specific CTLs that are not functionally suppressed or exhausted.

The APPART single center translational pilot study is designed to investigate the molecular properties and anti-tumor cytolytic function of T-lymphocytes isolated from the vermiform appendix sana of PDAC patients.

The APPART study may open up doors for T-cell transfer therapy and improvement of immune therapy for PDAC.

#### Study objective

We hypothesize that tumor antigens are presented to naïve T-lymphocytes in the gut associated lymphoid tissue of the vermiform appendix to induce differentiation to cytotoxic T cells in patients with PDAC.

#### Study design

Three time points: plasma and PBMCs before appendectomy; mononuclear cells from the appendix; PBMCs after appendectomy

#### Intervention

Peripheral venous blood draws, appendectomy during standard of care (laparoscopic) surgery, liver and peritoneal biopsies if metastases are visualized during staging laparoscopy

# Contacts

#### Public Erasmus Medisch Centrum Rotterdam

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# **Eligibility criteria**

# **Inclusion criteria**

Patients aged 18 years or older with treatment naïve pancreatic ductal adenocarcinoma who will either undergo staging laparoscopy for locally advanced disease, or tumor resection for (borderline) resectable disease.

### **Exclusion criteria**

prior appendectomy, prior malignancy within the past 5 years, prior chemotherapy or radiotherapy within the past 5 years, pregnancy, participation in the PREOPANC-2 trial.

# Study design

### Design

Study type:InterventionalIntervention model:OtherAllocation:Non controlled trialMasking:Open (masking not used)Control:N/A , unknown

### Recruitment

NL Recruitment status: Re Start date (anticipated): 15

Recruitment stopped 15-02-2019

3 - APPART study 4-05-2025

Enrollment:	50
Туре:	Actual

# **IPD sharing statement**

Plan to share IPD: Undecided

# **Ethics review**

Positive opinionDate:25-02-2019Application type:First submission

# **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
NTR-new	NL7553
Other	METC Erasmus Medisch Centrum : MEC-2018-1510

# **Study results**