Establishing organoids from metastatic pancreatic cancer patients, the OPT-I study

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To develop a model system and infrastructure to individualize the treatment of patients with advanced pancreatic adenocarcinoma. Additionally, we aim to identify predictors of therapy (non)response.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON55389

Source
ToetsingOnline

Brief title
OPT-I

Condition

- Metastases

Synonym
pancreatic adenocarcinoma, pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting overleven met alvleesklierkanker

Intervention

Keyword: metastatic, organoids, pancreatic cancer

Outcome measures

Primary outcome

The development of organoids from biopsies of metastases or primary tumour tissue of pancreatic cancer. The response of the organoids will be assessed for correlation with clinical response.

Secondary outcome

The expression of bio markers in organoid, organotypic and xenograft models will be investigated. DNA/RNA profiles will be correlated to clinical and pathological characteristics such as therapy response, survival and TNM classification.

Study description

Background summary

Pancreatic adenocarcinoma is a malignancy with a poor prognosis. Resection is the only curative option and still 5-year survival rate is less than 10 percent. But most patients present with advanced disease and are provided with palliative care. The nature of the tumour and the intense stromal reaction around the tumour cells leave pancreatic adenocarcinoma relatively insensitive to chemotherapeutics. Current models, such as cell lines or patient derived xenografts, cannot provide predictive information in a clinically relevant timeframe. Organoids and organotypic culture systems have emerged as promising new culturing techniques that maintain some of the complexity of the tumour. As most patients are ineligible for tumour resection, this project will focus on metastases and will generate organoids from that tissue. Using a combination of organoids and organotypic systems, treatment (non)response can be predicted, which may provide a personalized treatment setting for patients with metastatic pancreatic adenocarcinoma.

Study objective

To develop a model system and infrastructure to individualize the treatment of patients with advanced pancreatic adenocarcinoma. Additionally, we aim to identify predictors of therapy (non)response.

Study design

Observational laboratory studies (with DNA/RNA isolation, RNA sequencing, cell culturing, organoid culturing and xenografting) will be performed with tumour specimens. Response to drug (combinations) will be tested. Additionally, these organoids will be stored for future research in a living organoid biobank.

Intervention

NA

Study burden and risks

Participating in this study requires a biopsy from the patient. The material will be obtained from the biopsy required for diagnosis or the patient is asked for consent for an additional tumour biopsy not required for diagnosis. The study could benefit patients not directly, but their organoids provide valuable information to start personalized therapy for patients with advanced pancreatic cancer. In further studies organoids can be used to assess efficacy of first-line treatment and when necessary may provide an advice for second-line treatment options. Additionally, future patients may benefit, if biomarkers are found to predict therapy (non)response.

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

- Patients older than 18 years
- Diagnosed with locally advanced pancreatic cancer or metastatic pancreatic cancer
- Able to understand the information given
- WHO 0-2

Exclusion criteria

- Unfit for biopsies & blood analyses in palliative chemotherapy studies
- Not able to give informed consent (language, intellectual capacities, etc.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-11-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.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	NL62539.018.17