Validatie van predictieve biomarkers voor FOLFIRINOX respons in patiënten met pancreascarcinoom

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21925

Source
NTR

Brief title
PANCAKE

Health condition

Pancreatic cancer

Sponsors and support

Primary sponsor: Erasmus University Medical Center, department of Surgery
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Differences in circulating tumor DNA, microRNAs, SNPs, and cytokines between patients with disease control and patients with progressive disease during FOLFIRINOX treatment and sensitivity and specificity of these biomarkers.

Secondary outcome

N/A

Study description

Background summary

Pancreatic ductal adenocarcinoma (PDAC) has a very high mortality rate, partially because of diagnosis at late stage of disease. Only 20% of patients present with resectable disease. Nowadays, the standard first-line treatment for locally advanced (LAPC) and metastatic PDAC is FOLFIRINOX chemotherapy, a combination of fluorouracil, leucovorin, irinotecan and oxaliplatin. Despite increased overall survival in FOLFIRINOX-treated patient groups, 20-30% of patients will already show progressive disease during chemotherapy treatment. In the meantime, 60-70% of patients experiences grade 3-5 toxicity from FOLFIRINOX treatment. Biomarkers, especially those that can be easily measured in the peripheral blood instead of tumor tissue, are necessary to stratify patients for available therapies. Being able to select only patients that will benefit from FOLFIRINOX chemotherapy could prevent non-responding patients from severe FOLFIRINOX-induced toxicity. These nonresponders might benefit from other types of (chemo)therapy instead. In a previous pilot study (iKnowIT), we found some promising candidate biomarkers, measured in the peripheral blood of PDAC patients, that might predict FOLFIRINOX response.

The aim of this study is to validate promising circulating predictive biomarkers for FOLFIRINOX response in patients with PDAC, including circulating tumor DNA mutations, microRNAs, single nucleotide polymorphisms (SNPs) and cytokines, and to generate a biobank of blood samples to investigate future biomarkers.

Study objective

Validation of previously found predictive biomarkers for FOLFIRINOX response

Study design

Differences in ctDNA, miRNAs, SNPs, and cytokines will be measured in blood samples drawn before start of the first cycle of FOLFIRINOX and before start of the second cycle of FOLFIRINOX. Patients will be grouped according to the RECIST chemotherapy response: disease control or progressive disease. These results are available from the final response evaluation after 8 cycles of FOLFIRINOX.

Final analysis on all data, including patient characteristics, survival outcome, response outcome, and biomarker data will take place 2.5 years after full inclusion. After 2.5 years response outcome will be available for all patients.

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18 years.
• Diagnosed with (borderline) resectable, locally advanced or metastatic PDAC.
• Treatment with FOLFIRINOX chemotherapy, including neoadjuvant therapy in the investigational group ór treatment with gemcitabine (with nab-paclitaxel) in the control group.
• Written informed consent (either for PANCAKE in case of locally advanced PDAC and metastasized PDAC or for the PREOPANC-3 trial in case of (borderline) resectable PDAC).

Exclusion criteria

• Combined treatment with other chemotherapeutics then FOLFIRINOX.
• Previous treatment with FOLFIRINOX chemotherapy.
• Pregnancy.
• 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 non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-04-2021
Enrollment:	240
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-07-2021
Application 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	NL9609

Register	ID
Other	METC Erasmus MC : MEC-2021-0001

Study results