Validatie van predictieve biomarkers voor FOLFIRINOX respons in patiënten met pancreascarcinoom

Gepubliceerd: 07-07-2021 Laatst bijgewerkt: 13-12-2022

Validation of previously found predictive biomarkers for FOLFIRINOX response

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21925

Bron
NTR

Verkorte titel
PANCAKE

Aandoening

Pancreatic cancer

Ondersteuning

Primaire sponsor: Erasmus University Medical Center, department of Surgery
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Validation of previously found predictive biomarkers for FOLFIRINOX response

Onderzoeksopzet

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-04-2021
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9609
Ander register	METC Erasmus MC : MEC-2021-0001

Resultaten