Predictieve biomarkers voor FOLFIRINOX respons in patiënten met alvleesklierkanker

No registrations found.

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

Summary

ID

NL-OMON29299

Source
NTR

Brief title
iKnowIT

Health condition

Pancreatic cancer

Sponsors and support

Primary sponsor: Erasmus University Medical Center, department of Surgery
Source(s) of monetary or material Support: Eurostars, Stichting Coolsingel

Intervention

Outcome measures

Primary outcome

Differences in SNPs, ctDNA (mutations), circulating miRNA, oral microbiome and immune profiles between responders and nonresponders to FOLFIRINOX chemotherapy.

Secondary outcome

Differences in SNPs, ctDNA (mutations), circulating miRNA, oral microbiome and immune profiles between patients who experience severe (grade 3 or 4) toxicity and patients who do not experience severe toxicity due to FOLFIRINOX treatment.
Also: response rate, number of adverse events, resection rate, progression free survival, overall survival.

Study description

Background summary

FOLFIRINOX chemotherapy (a combination of folinic acid/Leucovorin, Fluorouracil, Irinotecan and Oxaliplatin) is the best treatment and the standard of care for patients with locally advanced or metastatic pancreatic cancer. However, only 30% of patients show response to treatment and more than 60% of all treated patients will experience a grade 3 or 4 adverse event caused by toxicity of the chemotherapy. At this moment, there are no biomarkers available which can predict response to FOLFIRINOX chemotherapy. Adequate selection of patients, preferably based on the use of a validated biomarker from peripheral blood sampling, will prevent unnecessary deterioration of their quality of life and reduce health care costs substantially.

The aim of this study is to investigate whether there are differences in several biomarkers (e.g. microRNAs or circulating tumor DNA) between responders and non-responders to FOLFIRINOX chemotherapy and between patients who experience severe toxicity and patients who do not experience severe toxicity due to FOLFIRINOX chemotherapy.

Study objective

Investigation of different biomarkers to predict response in pancreatic cancer patients, treated with FOLFIRINOX chemotherapy.

Study design

Final analysis will take place 2 years after full inclusion.

Contacts

Public
Erasmus University Medical Center
Fleur van der Sijde

0642101567
Scientific
Erasmus University Medical Center
Fleur van der Sijde

0642101567

Eligibility criteria

Inclusion criteria

 Age ≥ 18 years.
 Diagnosed with (borderline) resectable, locally advanced or metastasized PDAC.
 Treatment with FOLFIRINOX chemotherapy, including neoadjuvant and adjuvant therapy.
 Written informed consent

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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2018
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-02-2019
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	NL7522
Other	METC Erasmus MC : MEC-2018-087

Study results