New biomarkers for prediction of response to FOLFIRINOX chemotherapy in pancreatic cancer patients.

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To investigate whether there are differences in single nucleotide polymorphism*s (SNPs), circulating tumor DNA (ctDNA), micro RNA (miRNA) and immune profiles between responders and non-responders to FOLFIRINOX chemotherapy and between patients who...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Observational invasive

Summary

ID

NL-OMON46821

Source
ToetsingOnline

Brief title
iKnowIT

Condition

- Exocrine pancreas conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic ductal adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: EUROSTARS en Stichting Coolsingel

Intervention

Keyword: biomarkers, chemotherapy, FOLFIRINOX, pancreatic cancer

Outcome measures

Primary outcome

Differences in expression between responders and non-responders and between

patients who experience severe toxicity and those who do not, based on:

* SNPs

* ctDNA mutations

* miRNA patterns

* Microbiome patterns

* Immune profiles

Secondary outcome

* Response rate

* Number of adverse events

* Resection rate

* Progression free survival

* Overall survival.

Study description

Background summary

Pancreatic cancer has a very high mortality rate, partially because of diagnosis at late stage of disease. Only 20% of patients present with resectable disease. For all other patients FOLFIRINOX chemotherapy (a combination of Oxaliplatin, Leucovorin, Irinotecan and Fluorouracil) is the best treatment and the standard of care. 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. Previous studies have shown that certain single nucleotide polymorphisms (SNP*s) are associated with chemotherapy resistance. Changes in circulating tumor DNA and micro RNAs are thought to be of great value in indicating therapy response. Besides that, certain immune profiles may relate to different therapy responses, as described for other tumors.

Study objective

To investigate whether there are differences in single nucleotide polymorphism*s (SNPs), circulating tumor DNA (ctDNA), micro RNA (miRNA) and immune profiles 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 design

Prospective multicenter cohort study. 200 patients will be included over a period of 2 years. Blood samples will be drawn at two time points: before the first cycle and before the second cycle of FOLFIRINOX. After 4 cycles of FOLFIRINOX a CT scan will be performed to evaluate progression of disease.

Intervention

The intervention consists of 2 additional blood draws during a standard visit to the outpatient clinic. During each visit 5 additional tubes of blood (43 ml) will be collected.

Study burden and risks

Risks
Besides the slight chance of pain or bruising during the blood collection there are considered to be no extra risks in participating in this study.

Benefit
We expect that in the future patients diagnosed with pancreatic cancer can benefit from the results of this research.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age * 18 years
* Diagnosed with (borderline) resectable, locally advanced or metastasized pancreatic cancer
* 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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	08-06-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	24-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL65025.078.18