Next generation sequencing in patients with pancreatic ductal adenocarcinoma (PAN-NGS). A nationwide prospective, translational cohort study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21085

Source
Nationaal Trial Register

Brief title
PAN-NGS

Health condition

Pancreatic cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Merus N.V.

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study is defined as the frequency of clinically actionable

alterations in PDAC patients ≤ 60 years old.

Secondary outcome

• To assess the feasibility of nationwide NGS in a clinically relevant manner in the Netherlands.
• To determine the impact of NGS on clinical management in PDAC patients ≤ 60 years.
• To identify subgroups of PDAC patients with a high incidence of actionable genetic alterations.
• To identify genomic predictors of therapy response and long term oncological outcomes.
• To determine the potential of ctDNA for the identification of genetic alterations in pancreatic cancer patients.

Study description

Background summary

Pancreatic cancer is an aggressive disease that is difficult to treat. Some of the patients undergo surgery to remove the tumor. Unfortunately, in many patients, the pancreatic cancer comes back after it is surgically removed. The treatment for metastatic pancreatic cancer is usually chemotherapy. This chemotherapy offers only limited gains in survival. This is because it usually does not work for a long time. So there is need for new and better treatment methods.
Pancreatic cancer is caused by genetic abnormalities in the tissue of the pancreas. Some of these abnormalities can be treated with targeted drugs. Most patients with pancreatic cancer have genetic abnormalities for which unfortunately there is no effective medicine (yet). In this study we try to get a better picture of which genetic abnormalities are present in the tumors of relatively young pancreatic cancer patients. We are particularly interested in possible genetic abnormalities which can be treated with targeted drugs. These treatments are currently only given to patients who no longer respond to chemotherapy and only within a clinical trial context .

Study objective

This is an observational study which aims to determine the prevalence of actionable genetic alterations in pancreatic cancer patients up to 60 years old.

Study design

All patients will undergo a screening and baseline visit. For patients where no tumor tissue is available a biopsy will be performed to obtain tissue for NGS. Patients will be informed about the results of the NGS by their physician during a standard hospital visit. The results are expected about 3-4 weeks after material has been sent to the party who performs the NGS.

Primary endpoint
This endpoint will be determined after LPLV. The percentage of patients with clinically actionable alterations will be calculated by dividing the number of patients with an actionable genetic alteration by the total number of included patients with non-missing data.

Secondary endpoints
• To assess the feasibility of nationwide NGS in a clinically relevant manner in the Netherlands.
Feasibility is a composite endpoint of 1) the number of included patients within a one year period, 2) the percentage of patients successfully undergoing NGS and 3) results reported back to the local clinician within relevant time-frame. If all criteria are met, nationwide NGS is deemed feasible.
• To determine the impact of NGS on clinical management in PDAC patients ≤ 60 years.
Percentage of patients potentially experiencing a change in clinical management as result of the NGS. This is a change in treatment or referral to the clinical geneticist as a result of the NGS.
• To identify subgroups of PDAC patients with a high incidence of actionable genetic alterations.
For the identification of subgroups with more clinically actionable mutations, the incidence will be compared between pre-specified subgroups based on baseline variables, including; age (age < 50 years vs. age 50-60 years), gender, smoking status, disease status (primary, metastatic), tumor biopsy site, metastatic sites, treatment status (treatment naïve, neoadjuvant chemo(radio)therapy), oncologic history and familial history.
• To identify genomic predictors of therapy response and long term oncological outcomes.
Therapy outcomes and long term oncological outcomes include response to (systemic) therapy, toxicity of systemic therapy, recurrence free survival after resection, progression free survival and overall survival.
• To determine the potential of ctDNA for the identification of genetic alterations in pancreatic cancer patients.
The concordance rate for individual genes and the overall concordance rate (all genes in the ctDNA panel) in ctDNA alterations compared to tumor tissue NGS DNA alterations.

All secondary outcomes will be assessed after the inclusion period of 1 year has been completed so after LPLV.

Intervention

Peripheral blood collection and an additional biopsy in a subset of included patients.

Contacts

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Eligibility criteria

Inclusion criteria

• Cytological or histologically confirmed PDAC, irrespective of treatment status;
• Age > 18 years and ≤ 60 years at date of primary diagnosis;
• Performance status of ECOG 0-2;
• Estimated life expectancy of at least 12 weeks;
• Written informed consent.

Exclusion criteria

• Unwilling to know if there are any alterations which might be associated with genetic predisposition of cancer;
• Patient with locally-advanced PDAC or local-recurrence of PDAC with no histological tissue available for NGS.

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:	Pending
Start date (anticipated):	05-11-2020
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 51960
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9040
CCMO	NL75415.078.20
OMON	NL-OMON51960

Study results