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

Gepubliceerd: 05-11-2020 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21085

Bron
NTR

Verkorte titel
PAN-NGS

Aandoening

Pancreatic cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Merus N.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is defined as the frequency of clinically actionable alterations in PDAC patients ≤ 60 years old.

Toelichting onderzoek

Achtergrond van het onderzoek

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 .

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Erasmus MC
Gaby Strijk

010-7044331

Wetenschappelijk

Erasmus MC
Gaby Strijk

010-7044331

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-11-2020
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51960
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten