Pancreatic Cancer Surveillance in CDKN2A and Other High Risk Mutation Carriers

Gepubliceerd: 14-12-2020 Laatst bijgewerkt: 15-05-2024

Our hypothesis is that surveillance for pancreatic cancer in CDKN2A and other high risk mutation carriers leads to increased short and long term survival, as compared to pancreatic cancer diagnosed in the general population.

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

Samenvatting

ID

NL-OMON27120

Bron
Nationaal Trial Register

Verkorte titel
PARSEC

Aandoening

Pancreatic cancer

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The 5-year survival rate of patients with a CDKN2A mutation undergoing surveillance who develop PC.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Pancreatic cancer (PC) surveillance programs for high risk individuals, such as CDKN2A mutation carriers, require continuous evaluation and improvement.
Objective: The primary objective is to study if PC surveillance in individuals with a CDKN2A or other high risk mutations leads to an increase of 5-year survival rate, as compared to PC in the general population. Secondary objectives are: (1) to study long-term survival; (2) to identify additional risk factors that predict neoplastic progression in order to improve risk stratification; (3) to evaluate the accuracy of MRI/MRCP and EUS for detecting neoplastic lesions; (4) to investigate the role of ct-DNA as a diagnostic and prognostic marker; (5) to investigate the molecular characteristics of CDKN2A PDAC; (6) to study the cost-effectiveness of pancreatic surveillance; and (7) to explore the psychological aspects of genetic testing and surveillance.
Study design: This study is a registry of CDKN2A and other high risk mutation carriers enrolled in the Leiden University Medical Center PC surveillance program.
Study population: All individuals ≥ 40 and ≤ 75 years of age with a proven CDKN2A mutation and other high risk mutation carriers.
Main study endpoint: The main study endpoint is the 5-year survival rate of patients with a CDKN2A mutation undergoing surveillance who develop PC.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The majority of the data that will be collected in this study is part of routine care. As a study procedure, we will collect two extra blood samples during annual blood sampling, which is part of routine care. In addition, with subset of participants (30 individuals) we will conduct a focus-group study (in-depth interview), which will last a maximum of 2 hours. We feel that the risks and burden in this study are neglectable. We expect that the study outcomes may be directly beneficial for (future) individuals participating in our surveillance program, and individuals participating in surveillance programs in other expert centers.

Doel van het onderzoek

Our hypothesis is that surveillance for pancreatic cancer in CDKN2A and other high risk mutation carriers leads to increased short and long term survival, as compared to pancreatic cancer diagnosed in the general population.

Onderzoeksopzet

The primary outcome (survival rate) will be evaluated in 2021.

Onderzoeksproduct en/of interventie

Annual magnetic resonance imaging (MRI) with or without endoscopic ultrasound (EUS)

Contactpersonen

Publiek

Leiden University Medical Center
Derk Klatte

071-526 3507

Wetenschappelijk

Leiden University Medical Center
Derk Klatte

071-526 3507

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Participating in the PC surveillance program, which requires:
• A proven CDKN2A or LKB1/STK11 mutation and ≥ 40 years old
• A proven BRCA1, BRCA2, PALB2, ATM, MLH1, MSH2, or MSH6 mutation with at least one affected first degree blood relative with pancreatic cancer and ≥ 45 years old.
• Screening for all mutation carriers ends at the age of 75 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Comorbidity leading to an impaired physical performance (World health organization (WHO) performance status 3-4) or mental retardation
• Life expectancy < 5 years.
• Very limited understanding of the Dutch or English language to be able to make an informed choice.

• No informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	280
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	14-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50801
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9158
CCMO	NL75802.058.21
OMON	NL-OMON50801

Resultaten

Samenvatting resultaten
N/A