Pancreatic cancer surveillance in CDKN2A and other high risk mutation carriers

Published: 23-03-2021
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON50801

Source
ToetsingOnline

Brief title
PARSEC

Condition

- Congenital and hereditary disorders NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
'p16-Leiden', pancreatic malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ct-DNA onderzoek en vragenlijst onderzoek wordt sponsoring voor aangevraagd

Intervention

Keyword: CDKN2A, Imaging, Pancreatic cancer, Surveillance

Outcome measures

Primary outcome

The main study endpoint is the 5-year survival rate of patients with a CDKN2A mutation undergoing surveillance who develop PC.

Secondary outcome

1) The 10-year survival rate of individuals with a high risk mutationof patients with a CDKN2A mutation undergoing surveillance who develop PC.

2) Identification of risk factors that predict neoplastic progression and development of PC.

3) The accuracy of MRI/MRCP and EUS for detecting neoplastic lesions, as compared to histology as a reference.

4.1) The accuracy and feasibility of ct-DNA to detect PDAC.

4.2 The correlation between ct-DNA levels and PC stage.

4.3) The correlation between ct-DNA with CEA and CA 19-9 tumormarkers.

5) To explore the molecular profile of CDKN2A PDAC as compared to sporadic PDAC (PDAC occurring in the general population).

6) Cost-effectiveness of pancreatic surveillance.

7) Exploration of psychological aspects of screening, including knowledge and perceptions of benefits and risks of genetic testing and surveillance.

Study description

Background summary

Pancreatic cancer (PC) is a highly lethal malignancy. Early detection is challenging due to the lack of recognizable symptoms in its early stages. Although screening and detection of early PC and its precursor lesions may improve outcomes, general population-based screening for average-risk individuals is not recommended, because the average lifetime risk for developing PC is too low. However, in individuals with a strong family history and/or genetic susceptibility, pancreatic surveillance has the potential to increase overall survival. Therefore, The International Cancer of the Pancreas Screening (CAPS) Consortium guideline recommends pancreatic surveillance to detect early PC and high-grade precursor lesions in high risk mutation carriers, such as CDKN2A. Pancreatic surveillance should be organized in a study setting which enables us to continuously evaluate and improve our surveillance programs.

Study 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 burden and risks

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 (24-30 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must be participating in the LUMC PC surveillance program, which requires:
- aged between 40 and 75, and
i) a proven CDKN2A or LKB1/STK11 mutation, regardless of family history, or
ii) a BRCA1/2, PALB2, ATM, MLH1/MSH2/MSH6 mutation with at least one first degree relative with PC.

Exclusion criteria

- 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.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2022
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO

Date:	23-03-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27120
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75802.058.21
OMON	NL-OMON27120