# Pancreatic Cancer Surveillance in CDKN2A and Other High Risk Mutation Carriers

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON27120

**Source**
Nationaal Trial Register

**Brief title**
PARSEC

**Health condition**

Pancreatic cancer

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center
**Source(s) of monetary or material Support:** Initiator = sponsor

### Intervention

### Outcome measures

**Primary outcome**

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

### Secondary outcome

1) The 5-year survival rate of individuals with other (non-CDKN2A) high risk mutations undergoing surveillance who develop PC.
2) The 10-year survival rate of all individuals with a high risk mutation undergoing surveillance who develop PC.
3) Identification of risk factors that predict neoplastic progression and development of PC.
4) The accuracy of MRI/MRCP and EUS for detecting neoplastic lesions, as compared to histology as a reference.
5) Ct-DNA:
5.1) The accuracy and feasibility of ct-DNA to detect PDAC
5.2) The correlation between ct-DNA levels and PC stage.
5.3) The correlation between ct-DNA with CEA and CA 19-9 tumormarkers
6) To explore the molecular profile of CDKN2A PDAC as compared to sporadic PDAC (PDAC occurring in the general population).
7) Assess the cost-effectiveness of pancreatic surveillance in high risk mutation carriers.
8) Exploration of psychological aspects of screening, including knowledge and perceptions of benefits and risks of genetic testing and surveillance.

## Study description

### Background summary

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.

### Study objective

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.

### Study design

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

### Intervention

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

## Contacts

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Leiden University Medical Center
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## Eligibility criteria

### Inclusion criteria

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.

### 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

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| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2021 |
| Enrollment: | 280 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
N/A

## Ethics review

Positive opinion
Date: 14-12-2020
Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 50801
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results

**Summary results**
N/A