

# Screening newly diagnosed diabetics for pancreatic cancer using a blood and urine test

|  |  |  |
|--|--|--|
| <b>Submission date</b><br>18/09/2018   | <b>Recruitment status</b><br>Stopped   | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>01/10/2018 | <b>Overall study status</b><br>Stopped | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>08/10/2024       | <b>Condition category</b><br>Cancer    | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English Summary

Current plain English summary as of 28/05/2020:

### Background and study aims

Type 2 diabetes is one of the most common diagnoses in Swiss family practices. The incidence of diabetes increases with age - by 75 years old, nearly 1/3 of the population has diabetes.

About 80% of pancreatic cancer patients have elevated blood sugar or diabetes. Newly discovered diabetes can be an early symptom of pancreatic cancer. Studies show that these patients already have elevated HbA1c (a marker of diabetes) levels up to 5 years prior to a pancreatic cancer diagnosis when compared to healthy individuals. This diabetes usually disappears after a successful operation on the pancreas.

The hypothesis is that newly diagnosed diabetics are a high-risk group for pancreatic cancer and eligible for screening. The intention is to measure the frequency of pancreatic cancer in newly diagnosed diabetic and prediabetic patients, and to show that the PancRISK score (a new test) with serum CA 19-9 (an already used blood test) is a suitable screening method.

### Who can participate?

People with newly diagnosed diabetes mellitus. Participants should also have at least one of the risk factors for pancreatic cancer - aged over 50 years older, smokers, family history of pancreatic cancer, chronic pancreatitis or gestational diabetes.

### What does the study involve?

Patient's height, weight, blood pressure and medical history will be taken and recorded by the family doctor, along with blood and urine samples. The blood and urine samples will then be used for screening for pancreatic cancer. If participants test positive for pancreatic cancer in these tests, an MRI scan will be done to determine whether they have pancreatic cancer.

Patients who are suspected of having pancreatic cancer after these scans will be referred to a specialist for treatment (treatment is not part of this study). If participants test negative for pancreatic cancer in the initial tests or after the CT scan, they will be regularly screened for pancreatic cancer every 3-6 months for 3 years. If they do show symptoms of pancreatic cancer in these follow-up screenings, they will be referred to the researchers.

Where is the study run from?  
Spital Freiburg (Switzerland)

When is the study starting and how long is it expected to run for?  
November 2020 to December 2030

Who is funding the study?  
The study will be funded through grant money

Who is the main contact?  
Dr med. Claudia Mellenthin  
dr.mellenthin@hin.ch

Previous plain English summary:

#### Background and study aims

Type 2 diabetes is one of the most common diagnoses in Swiss family practices. The incidence of diabetes increases with age - by 75 years old, nearly 1/3 of the population has diabetes. About 80% of pancreatic cancer patients have elevated blood sugar or diabetes. Newly discovered diabetes can be an early symptom of pancreatic cancer. Studies show that this patients already have elevated HbA1c (a marker of diabetes) levels up to 5 years prior to a pancreatic cancer diagnosis when compared to healthy individuals. This diabetes usually disappears after a successful operation on the pancreas.

The hypothesis is that newly diagnosed diabetics or prediabetics (those who are not matching the criteria of diabetes, but have slightly elevated blood sugar) are a high-risk group for pancreatic cancer and eligible for screening. Our intention is to measure the frequency of pancreatic cancer in newly diagnosed diabetic and prediabetic patients, and to show that the combination of the urine 3-biomarker test (a new test) with serum CA 19-9 (an already used blood test) is a suitable screening method.

#### Who can participate?

People with newly diagnosed diabetes mellitus or newly diagnosed prediabetes. Participants should also have at least one of the risk factors for pancreatic cancer - aged over 50 years older, smokers, family history of pancreatic cancer, chronic pancreatitis or gestational diabetes.

#### What does the study involve?

Patient's height, weight, blood pressure and medical history will be taken and recorded by the family doctor, along with blood and urine samples. The blood and urine samples will then be used for screening for pancreatic cancer. If participants test positive for pancreatic cancer in these tests, they will have a test for kidney function. If kidney function is normal, a CT scan will be done to determine whether they have pancreatic cancer (if patients have kidney failure, they will have an MRI scan instead of a CT scan). Patients who are suspected of having pancreatic cancer after these scans will be referred to a specialist for treatment (treatment is not part of this study).

If participants test negative for pancreatic cancer in the initial tests or after the CT scan, they will be regularly screened for pancreatic cancer every 3-6 months for 2 years. If they do show symptoms of pancreatic cancer in these follow-up screenings, they will be referred to the Swiss Pancreas Center.

Where is the study run from?  
Swiss Pancreas Center, Bern (Switzerland)

When is the study starting and how long is it expected to run for?  
June 2016 to September 2023

Who is funding the study?  
Schweizer Pankreasstiftung (Switzerland)

Who is the main contact?  
Dr. med. Claudia Mellenthin  
dr.mellenthin@hin.ch

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Claudia Mellenthin

**Contact details**  
Chemin de Pennsionat 2-4  
Freiburg  
Switzerland  
1700  
+41 (0)797543292  
dr.mellenthin@hin.ch

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
Pancreatic Cancer Testing in Emerging Diabetes (PACTED) using a urine 3-biomarker panel (LYVE1, REG1B, TFF1) and Serum CA 19-9

**Acronym**  
PACTED

**Study hypothesis**

Current study hypothesis as of 28/05/2020:

The hypothesis is that newly diagnosed diabetics are a high-risk group for PDAC and eligible for screening. The intention is therefore to measure the prevalence of PDAC in newly diagnosed diabetic and prediabetic patients, and to show that the combination of the urine 3-biomarker panel with serum CA 19-9 is a suitable screening method.

Previous study hypothesis:

The hypothesis is that newly diagnosed diabetics or prediabetics are a high-risk group for PDAC and eligible for screening. The intention is therefore to measure the prevalence of PDAC in newly diagnosed diabetic and prediabetic patients, and to show that the combination of the urine 3-biomarker panel with serum CA 19-9 is a suitable screening method.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval will be sought prior to recruitment

### **Study design**

Observational exploratory regional single-centre cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

GP practice

### **Study type(s)**

Screening

### **Participant information sheet**

No participant information sheet available

### **Condition**

Pancreatic cancer, diabetes

### **Interventions**

Current interventions as of 28/05/2020:

Participants' personal information and medical history will be collected, along with blood and urine samples. Measurements of HbA1c and CA-19-9 will be taken from the blood and urine samples, along with a 3-biomarker panel. In those who test positive for PDAC in these first tests, a contrasted abdominal MRI scan will be performed. Those testing negative from the biomarker test or MRI scan will have regular screening for PDAC every 3-6 months for 3 years by their family doctor.

Previous interventions:

Participants' personal information and medical history will be collected, along with blood and urine samples. Measurements of HbA1c and CA-19-9 will be taken from the blood and urine

samples, along with a 3-biomarker panel. In those who test positive for PDAC in these first tests, serum creatinine will be measured to assess kidney function. If there is no contraindication (i.e. if kidney function is normal), a contrasted abdominal CT scan will be performed (in case of a contraindication (kidney failure), an MRI scan will be done instead). Those testing negative from the biomarker test or CT scan will have regular screening for PDAC every 3-6 months for 2 years by their family doctor.

## **Intervention Type**

Other

## **Primary outcome measure**

Screening prevalence of PDAC in both screened populations, determined as the proportion of screened patients who have a positive screening test for PDAC with a confirmed CT diagnosis, or diagnosed during the 3-year follow-up

Updated 28/05/2020: follow-up changed from 2 years to 3 years.

## **Secondary outcome measures**

1. Diagnostic performance of the urine 3-biomarker panel with serum CA19-9, assessed at predefined thresholds using the numbers of true positives, false positives, true negatives and false negatives from this test

1.1. The receiver operating characteristic (ROC)

1.2. Area under the curve (AUC)

1.3. Sensitivity

1.4. Specificity

1.5. Predictive values

1.6. Probability values

As a gold standard, we use a CT to confirm positive screening tests, and a 3-year follow-up to confirm negative tests

2. Mean survival of PDAC patients who were diagnosed at the screening, assessed using Kaplan-Meier curves, assessed at the 3-year follow-up

3. Stage of the PDAC at diagnosis, assessed using the numbers of participants with each stage of PDAC

Updated 28/05/2020: follow-up changed from 2 years to 3 years.

## **Overall study start date**

02/06/2016

## **Overall study end date**

30/12/2030

## **Reason abandoned (if study stopped)**

Lack of funding/sponsorship

# **Eligibility**

## **Participant inclusion criteria**

Either:

Newly diagnosed diabetes mellitus, defined as HbA1c >6.5% (diagnosed within 1 month before inclusion)

Or:  
Newly diagnosed prediabetes, defined as HbA1c > 6 % at two occasions with an interval of  $\geq 6$  months (second measurement within the last month)  
Participants should also have one or more of the following risk factors of PDAC:

1. Aged 50 years or older
2. Smoking
3. Positive family history for PDAC
4. Status post gestational diabetes
5. Chronic pancreatitis

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

1000

**Participant exclusion criteria**

1. Inability to follow the procedures of the study or missing ability to provide informed consent (e.g. due to age, language, psychological factors, dementia, etc)
2. Known PDAC
3. Other preexisting gastrointestinal cancers
4. Pregnancy
5. Known severe renal insufficiency (Clearance <30 ml)
6. Aged below 18 years

Updated 28/05/2020:

6. Aged below 40 years

**Recruitment start date**

01/06/2019

**Recruitment end date**

01/09/2021

**Locations**

**Countries of recruitment**

Switzerland

**Study participating centre**

Klinik für Chirurgie

Freiburger Spital

Freiburg

Switzerland  
1700

## Sponsor information

### Organisation

Spital Freiburg

### Sponsor details

c/o Dr med. Claudia Mellenthin  
Chirurgische Klinik  
Freiburg  
Switzerland  
1700  
+41 (0)797543292  
dr.mellenthin@hin.ch

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/01q9sj412>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Spital Freiburg

## Results and Publications

### Publication and dissemination plan

We plan to publish our data on the screening results as soon as the 3-year follow up of the last patient is terminated and data analysis is completed. Publications will follow the standards of STARD37 and STROBE41, to ascertain high-quality reporting. Our secondary endpoint of survival will take longer to assess and will therefore be published later.

### Intention to publish date

01/03/2030

### **Individual participant data (IPD) sharing plan**

Data will only be shared anonymized and after we have been assured of the adequate data protection standards of the interested parties, if their intent is relevant for the goal of developing a screening program and if the reputation of the requesting research team is acceptable.

### **IPD sharing plan summary**

Other