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

Submission date 18/09/2018	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/10/2018	**Overall study status** Stopped	
Last Edited 08/10/2024	**Condition category** Cancer	

Plain English summary of protocol

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
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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 slighly 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 objectives
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

Study type(s)
Screening

Health condition(s) or problem(s) studied
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(s)
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.

Key secondary outcome(s))
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.

Completion date
30/12/2030

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key 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 ≥ 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

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key 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 insufficency (Clearance <30 ml)
6. Aged below 18 years

Updated 28/05/2020:
6. Aged below 40 years

Date of first enrolment
01/06/2019

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
Switzerland

Study participating centre
Klinik für Chirurgie
Freiburger Spital
Freiburg
Switzerland
1700

Sponsor information

Organisation
Spital Freiburg

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Spital Freiburg

Results and Publications

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