

# UK early detection initiative for pancreatic cancer

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| <b>Submission date</b><br>13/01/2020   | <b>Recruitment status</b><br>Recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>13/02/2020 | <b>Overall study status</b><br>Ongoing  | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>09/07/2025       | <b>Condition category</b><br>Cancer     | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-finding-pancreatic-cancer-early-uk-ed>

### Background and study aims

At the time of diagnosis of pancreatic cancer, an estimated 65% of patients have diabetes mellitus. Whilst in some individuals with pancreatic cancer the diabetes is long-standing, the remainder is new-onset diabetes. This often goes undiagnosed and when it is diagnosed, in the majority of cases the diabetes develops within one year prior to pancreatic cancer being identified. New-onset diabetes can therefore be an early warning sign in a proportion of individuals of the presence of pancreatic cancer.

Only a small proportion of individuals who develop new-onset diabetes (1 in 100) develop the diabetes as a result of undiagnosed pancreatic cancer. Currently there are no reliable tests to identify which individuals have developed diabetes as a result of undiagnosed pancreatic cancer. It is therefore not possible to screen everybody who develops new-onset diabetes to test if this is as a result of having pancreatic cancer.

This study aims to recruit 1000 individuals with new-onset diabetes in order to collect blood samples and clinical data. The researchers hope to identify biomarkers in the blood that will be able to distinguish if diabetes has been caused by pancreatic cancer or not. The researchers will also attempt to gain a better understanding of risk factors associated with pancreatic cancer and to determine the cost-effectiveness of screening for pancreatic cancer. This may ultimately enable a screening programme in the future.

### Who can participate?

Patients aged 50 or over with new-onset diabetes diagnosed within 6 months of study entry, no previous history of pancreatic cancer, no previous surgery of the pancreas.

### What does the study involve?

The study involves attending the research site on five occasions six months apart. Blood samples for research and clinical data are collected at each visit

### What are the possible benefits and risks of participating?

This is an observational scientific research study. It is unlikely that the study will be of direct

benefit to participants. It is hoped however that this research will eventually lead to improvements in screening for, and diagnosis of, pancreatic cancer. There may be some minor but short-lasting discomfort when providing a blood sample

Where is the study run from?

The study is co-ordinated by the Liverpool Clinical Trials Centre within the University of Liverpool (UK)

When is the study starting and how long is it expected to run for?

April 2019 to June 2026

Who is funding the study?

Cancer Research UK

Who is the main contact?

Mr Robert Hanson

ukedi@liverpool.ac.uk

### **Study website**

<http://www.uk-edi.co.uk>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Mr Robert Hanson

### **Contact details**

University of Liverpool

Liverpool Clinical Trials Centre

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

258093

### **ClinicalTrials.gov number**

Nil known

## Secondary identifying numbers

CPMS 42837, IRAS 258093

# Study information

## Scientific Title

UK Early Detection Initiative for pancreatic cancer (UK-EDI)

## Acronym

UK-EDI

## Study objectives

Current study objectives:

Developing methods for pancreatic cancer detection in individuals with new-onset DM will require early-stage, pre-diagnostic samples and corresponding patient data. In this study, the researchers aim to recruit 1000 Individuals from hospitals and GP surgeries who are 50 years old or over and newly diagnosed with DM. Blood samples and questionnaire/clinical data will be collected at appointments every six months for two years. The researchers will collect and store samples in a standardised way so that they can be used to identify biomarkers in the blood that will distinguish between DM caused by pancreatic cancer and type 2 DM. This may ultimately enable a screening programme in the future.

As part of this study, the researchers will also attempt to gain a better understanding of risk factors associated with pancreatic cancer and to determine the cost-effectiveness of screening for pancreatic cancer.

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Previous study objectives:

Developing methods for pancreatic cancer detection in individuals with new-onset DM will require early-stage, pre-diagnostic samples and corresponding patient data. In this study, the researchers aim to recruit 2500 Individuals from hospitals and GP surgeries who are 50 years old or over and newly diagnosed with DM. Blood samples and questionnaire/clinical data will be collected at appointments every six months for two years. The researchers will collect and store samples in a standardised way so that they can be used to identify biomarkers in the blood that will distinguish between DM caused by pancreatic cancer and type 2 DM. This may ultimately enable a screening programme in the future.

As part of this study, the researchers will also attempt to gain a better understanding of risk factors associated with pancreatic cancer and to determine the cost-effectiveness of screening for pancreatic cancer.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 14/02/2020, London – West London& GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8163; NRESCommittee. London-WestLondon@nhs.net), ref: 20/LO/0058

**Study design**

Observational cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

GP practice, Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Pancreatic cancer

**Interventions**

A prospective cohort design will be used to recruit a patient cohort with new-onset diabetes of 50 years of age or over. Biological samples along with demographic and clinical data will be collected. These data will be collected with the aim of establishing biomarkers that may assist in identifying pancreatic cancer at an earlier stage.

Following confirmation of eligibility, participants are registered onto the study. Participants will attend for five study-specific visits: baseline, 6 months from baseline, 12 months 18 months and 24 months.

At each visit participants will provide a blood sample for HbA1c analysis and donate blood samples for biomarker translational work. Participants will be asked to provide data on demographics, medical and drug history and to complete two questionnaires; EQ-5D-5L and the Diabetes Self Management Questionnaire (DSMQ).

A final national database search will be conducted at 36 months for each participant to establish their health status. This will not require participant attendance as a distinct research visit.

**Intervention Type**

Other

**Primary outcome measure**

As a scientific discovery study, there is no powered hypothesis test, however, the key clinical information the researchers are collecting is to define the incidence of pancreatic cancer in the

UK of individuals with new-onset diabetes. This is measured by confirmed clinical diagnosis of pancreatic cancer at 36 months from recruitment.

### **Secondary outcome measures**

As a scientific discovery study, there is no powered hypothesis test. The key clinical information the researchers are collecting is;

1. HbA1c measured using standard test on blood samples collected at baseline, 6, 12, 18 and 24 months
2. Quality of life measured using EQ-5D-5L at baseline, 6, 12, 18 and 24 months
3. Diabetes self-care activities measured using the Diabetes Self Management Questionnaire (DSMQ) at baseline, 6, 12, 18 and 24 months

### **Overall study start date**

01/04/2019

### **Completion date**

30/06/2026

## **Eligibility**

### **Key inclusion criteria**

1. Age  $\geq$  50 years at time of study entry
2. New-onset diabetes (defined as HbA1C  $\geq$  48mmol/mol (6.5%)) diagnosed within 6 months of study entry
3. Written informed consent obtained from the participant prior to performing any protocol-related procedures
4. Participant is willing and able to comply with the protocol for the duration of the study including scheduled follow-up visits

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

50 Years

### **Sex**

Both

### **Target number of participants**

1000

### **Key exclusion criteria**

Current exclusion criteria as of 09/07/2025:

1. Diagnosis or treatment of pancreatic cancer, peri pancreatic cancer or pancreatic endocrine cancer.
2. Previous surgical resection of the pancreas

3. Diagnosis of diabetes > 6 months before study entry
4. Pregnancy
5. Condition preventing study investigation and follow-up
6. Inability or incapacity to give informed consent

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Previous exclusion criteria:

1. Diagnosis of pancreatic cancer within 5 years of study entry
2. Treatment for digestive or endocrine cancer within 5 years of study entry
3. Previous surgical resection of the pancreas
4. A known history of hyperglycaemia/pre-diabetes (HbA1c: 42-47 mmol/mol (5.9% - 6.4%)) of greater than 3 years duration
5. Diagnosis of diabetes > 6 months before study entry
6. Pregnancy
7. Condition preventing study investigation and follow-up
8. Inability or incapacity to give informed consent

**Date of first enrolment**

08/02/2021

**Date of final enrolment**

30/12/2025

## Locations

**Countries of recruitment**

England

Northern Ireland

United Kingdom

Wales

**Study participating centre**

**Royal Liverpool University Hospital**

Royal Liverpool and Broadgreen University Hospitals NHS Trust

Prescot Street

Liverpool

United Kingdom

L7 8XP

**Study participating centre**

**Royal Free Hospital**

Royal Free London NHS Foundation Trust

Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre**  
**The Royal London Hospital**  
Barts Health NHS Trust  
Whitechapel  
London  
United Kingdom  
E1 1BB

**Study participating centre**  
**John Radcliffe Hospital**  
Oxford University Hospitals NHS Foundation Trust  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**  
**Queens Medical Centre**  
Nottingham University Hospitals NHS Trust  
Trust Headquarters  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**  
**The Countess Of Chester Hospital**  
Countess Of Chester Hospital NHS Foundation Trust  
Health Park  
Chester  
United Kingdom  
CH2 1UL

**Study participating centre**

**St. James's University Hospital**  
Leeds Teaching Hospitals NHS Trust  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**  
**Abertawe Bro Morgannwg University LHB**  
One Talbot Gateway  
Seaway Drive  
Seaway Parade Industrial Estate  
Baglan  
Port Talbot  
United Kingdom  
SA12 7BR

**Study participating centre**  
**Belfast Health and Social Care Trust**  
Trust Headquarters  
A Floor - Belfast City Hospital  
Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

## **Sponsor information**

**Organisation**  
University of Liverpool

**Sponsor details**  
c/o Alex Astor  
Research Support Office  
2nd Floor Block D Waterhouse Building  
3 Brownlow Street  
Liverpool  
England  
United Kingdom  
L69 3GL  
+44 (0)1517948739  
sponsor@liv.ac.uk

**Sponsor type**



University/education

**Website**

<http://www.liv.ac.uk/>

**ROR**

<https://ror.org/04xs57h96>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Cancer Research UK; Grant Codes: C7690/A26881

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

1. Study protocol, statistical analysis plan not currently available. The researchers intend to publish the protocol subject to successful REC review
2. Peer-reviewed scientific journals
3. Internal report
4. Conference presentation
5. Publication on website

**Intention to publish date**

30/06/2026

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

The data sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 26/07/2023 | No             | No              |