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UK early detection initiative for pancreatic cancer

Submission date 13/01/2020	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/02/2020	**Overall study status** Ongoing	
Last Edited 09/07/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-finding-pancreatic-cancer-early-uk-edi

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
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Contact information

Type(s)
Scientific

Contact name
Mr Robert Hanson

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
258093

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s))
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

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Age >= 50 years at time of study entry
2. New-onset diabetes (defined as HbA1C > = 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

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
United Kingdom

England

Northern Ireland

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

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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes