

# Observing current practice in pancreatic cancer

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<b>Registration date</b> 22/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/10/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This is an observational study of a patient cohort that has pancreatic cancer. The study aims to assess the variation in practice and treatment across the UK. This includes defining current practice and understanding variability in the treatment and outcomes of patients with potentially resectable pancreatic cancer; establishing a collaborative network across the United Kingdom's specialist surgery providers of pancreatic surgery; establishing a stable cohort for the prospective evaluation of pancreatic cancer patients for future research via the Trials Within a Cohort methodology (TwIC); expediting the identification and recruitment of patients for clinical trials; facilitating the cost-effective running of future observational and interventional clinical trials; and, supporting existing research infrastructure by supporting tissue collection for national biobanks.

### Who can participate?

Patients aged over 18 years old newly diagnosed with suspected or proven pancreatic cancer and are on a potentially resectable cancer pathway

### What does the study involve?

Data will be collected from patient records. There are optional quality-of-life questionnaires and blood samples for participation in a biomarkers study looking into cancer recurrence.

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

As this is an observational study the risks are very low. There also may be no direct benefit to the patient themselves but it could help inform improvements in practice and treatment of future patients with pancreatic cancer.

### Where is the study run from?

University of Birmingham (UK)

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

July 2024 to October 2029

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Katie Worrallo, k.worrallo@bham.ac.uk

## Contact information

### Type(s)

Scientific, Principal investigator

### Contact name

Prof Keith Roberts

### Contact details

Queen Elizabeth Hospital  
Mindelsohn Way  
Edgbaston  
Birmingham  
United States of America  
B15 2GW  
+44 (0)121 371 4656  
Keith.Roberts@uhb.nhs.uk

### Type(s)

Public

### Contact name

Dr Katie Worrallo

### Contact details

Institute of Applied Health Research  
University of Birmingham  
Birmingham  
United Kingdom  
B15 2TT  
+44 (0)121 415 9106  
k.worrallo@bham.ac.uk

## Additional identifiers

### Integrated Research Application System (IRAS)

324726

### Protocol serial number

RG\_23-157

## Study information

### Scientific Title

Pancreatic cancer: Observations of Practice and Survival (PACOPS)

## **Acronym**

PACOPS

## **Study objectives**

Study aims:

1. To define current practice and understand variability in the treatment and outcomes of patients with potentially resectable pancreatic cancer
2. To establish a collaborative network across the United Kingdom's specialist surgery providers of pancreatic surgery
3. To establish a stable cohort for the prospective evaluation of pancreatic cancer patients for future research via the Trials Within a Cohort methodology (TwIC)
4. To expedite the identification and recruitment of patients for clinical trials
5. To facilitate cost-effective running of future observational and interventional clinical trials.
6. To support existing research infrastructure by supporting tissue collection for national biobanks

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 29/08/2024, London – Camden and Kings Cross (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8086, (0)207 104 8004, (0)207 104 8244; camdenandkingscross.rec@hra.nhs.uk), ref: 24/PR/0939

## **Study design**

Multicentre UK-based prospective cohort study

## **Primary study design**

Observational

## **Study type(s)**

Quality of life, Screening, Treatment

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

Variability in the treatment and outcomes of patients with potentially resectable pancreatic cancer

## **Interventions**

PACOPS is an observational cohort study for reporting trends of practice and variation in the treatment and management of pancreatic cancer across the UK and as a stable cohort from which trials can be run (Trial within a cohort, TwIC).

Despite the centralisation of surgery for pancreatic cancer, there is variation in the treatment and management of pancreatic cancer across the UK which has been shown to impact outcomes. Recent snapshot audits from the UK highlight this variation. These audits have also demonstrated the failure of teams to implement interventions recommended in the NICE pancreatic cancer guidelines. Reasons for failure are related to a lack of effective tools to measure implementation and how such implementation affects real-world outcomes. There is thus a need for a system to highlight variation in practice, how such variation affects outcomes and to highlight good and poor-performing teams.

This observational study involves the collection of routinely collected data from participants' medical records. There are two optional aspects to PACOPS. Participants can choose to complete quality of life questionnaires every 3 months post-op until 24 months. They can also choose to provide blood samples that will be collected at routine clinic appointments and used in research into biomarkers for signs of potential cancer recurrence. The study includes a 2-year follow-up where data on patients will be collected.

### **Intervention Type**

Other

### **Primary outcome(s)**

This study will collect a range of clinical- and patient-reported outcomes. There is no explicit primary outcome measure and all of the following will be assessed:

#### Clinician-reported outcomes

1. Resection rates of different treatment pathways in pancreatic cancer measured using data recorded in an online Case Report Form (CRF) at 6 months
2. Approaches to resectability across the UK, measured using data recorded in an online CRF at 6 months
3. Recurrence-free interval, measured using data recorded in an online CRF at 3 monthly intervals up to 24 months
4. Clinical and radiological patterns of pancreatic cancer recurrence, measured using clinical and radiological data recorded in an online CRF at 3-6 monthly intervals following surgery
5. Prognostic factors for asymptomatic pancreatic cancer recurrence, measured using data recorded in an online CRF at 3-6 monthly intervals following surgery
6. Compliance of unit practice with published NICE guidelines, measured by comparing current practice as determined by the study with NICE Guidelines at 3-6 monthly intervals following surgery

#### Patient-reported outcomes

Quality of life measured using EQ5D, EORTIC QLQ-C30, EORTIC QLQ-PAN26, EORTIC QLQ-CIPN20 questionnaires completed by patients at 3 monthly intervals up to 24 months

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

25/10/2029

## **Eligibility**

### **Key inclusion criteria**

1. Adult patients (aged >18 years) who are newly diagnosed with suspected or proven pancreatic cancer and are on a potentially resectable cancer pathway
2. Potentially resectable for this study is defined as any patient receiving or considered for treatment which may be potentially curative and thus includes upfront surgery and neoadjuvant pathways, regardless of the anatomical staging of the cancer
3. Ability to provide informed consent

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

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Key exclusion criteria**

Patients undergoing resection for chronic pancreatitis and for tumours arising outside the pancreas

**Date of first enrolment**

25/10/2024

**Date of final enrolment**

25/10/2027

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2GW

**Sponsor information**

Organisation

University of Birmingham

**ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

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

The datasets generated during and/or analysed during the current study are not expected to be made available. Data will be held on secure servers at the University of Birmingham, and higher-level data will be available via publication - no participant-level data will be made available to the public. Data can be requested for use in other ethically approved research.

**IPD sharing plan summary**

Not expected to be made available