ISRCTN90934212 https://doi.org/10.1186/ISRCTN90934212

Observing current practice in pancreatic cancer

Submission date
18/07/2024

Recruitment status
Recruiting

Registration date
22/10/2024

Overall study status
Ongoing

Last Edited
21/10/2024

Condition category
Cancer

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

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 QLQCIPN20 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
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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