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Precision Panc: Advancing personalised medicine treatment strategies for pancreatic cancer

Submission date
22/01/2018

Recruitment status
Suspended

Registration date
29/01/2018

Overall study status
Completed

Last Edited
20/09/2021

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
At present pancreatic cancer is the 3rd leading cause of cancer death in the western world with only 3% of patients surviving for 5 years or more. Therefore there is an urgent need to both optimise the use of current therapies by identifying responsive (or non-responsive) subgroups and to develop novel therapeutic approaches. The Precision Panc Master Protocol allows for the taking of either extra tissue from a patient's diagnostic biopsy or an additional specific trial biopsy as well as a blood sample. These samples are subjected to molecular profiling and allow for the patient to then be enrolled into a PRIMUS study.

Who can participate?
Adults aged patients aged 16 and older who have a pancreatic mass and are willing to undergo a tumour biopsy.

What does the study involve?
Patients with either suspected or confirmed pancreatic cancer are approached to take part in the study and given the Precision Panc Screening PIS. Participants are given time to consider trial participation and if they are willing to take part in the study they are screened onto the study. If the patient has suspected pancreatic cancer and are having a standard of care diagnostic biopsy, extra cores are taken at that time for the Precision Panc study. If pancreatic ductal adenocarcinoma is confirmed the patient are then given the registration PIS/consent which allows for molecular profiling to take place on the extra tissue taken for research. If the patient already has a diagnosis of pancreatic ductal adenocarcinoma they are asked to undergo and additional research biopsy for the study. All participants are also asked to provide a blood sample for research. The tissue (either the extra diagnostic tissue or the research biopsy) and blood sample are sent to Glasgow for molecular profiling and if enough tissue is available for profiling they may be eligible for an open PRIMUS study.

What are the possible benefits and risks of participating?
It cannot be guaranteed that taking part in this study will benefit participants directly. This is because we cannot be sure that we will identify changes in participant’s tumour make up that

will indicate that a specific treatment or clinical trial will work better than any other until the study is undertaken. However, participating in the first stage of Precision-Panc study, will enable the collection of tumour samples that can be studied in detail in the second stage of this study (if cancer diagnosis is made). This information from the tumour sample may help to determine which treatment or clinical trial is best suited to your specific cancer. Participants are invited to allow the study to take a further sample of tissue from participants pancreatic lesion or disease elsewhere such as liver or lung (if applicable), during your routine diagnostic procedure. Before a biopsy is carried out, the risks are discussed with participants directly by the clinical team who do the biopsy, and they obtain your consent for it (Screening Consent). They answer any questions that you may have about the biopsy. If you have been diagnosed with pancreatic cancer already, we will ask you to consent to undergo a new biopsy procedure to obtain samples for research use only. The biopsies can be obtained through interventional radiology procedure or endoscopic ultrasound. This has a few small risks due to discomfort with needles. Additional research samples are usually taken at the same time as participants diagnostic biopsy, so it should not cause you additional risk or inconvenience. However, there may be occasions where you are asked to have another biopsy if the previously obtained samples are not good enough for research purposes. There may be additional risks that we do not expect or do not know about.

Where is the study run from?
Glasgow Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
April 2017 to March 2022

Who is funding the study?
1. CRUK (UK)
2. Celgene (UK)

Who is the main contact?
Ms Judith Dixon-Hughes (Public)
judith.dixon@glasgow.ac.uk

Study website
www.precisionpanc.org

Contact information

Type(s)
Public

Contact name
Ms Judith Dixon-Hughes

ORCID ID
http://orcid.org/0000-0002-5596-4400

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number
184216

ClinicalTrials.gov number

Secondary identifying numbers
IRAS184216

Study information

Scientific Title
Precision Panc Master Protocol: Personalising Treatment for Pancreatic Cancer

Acronym
Precision Panc

Study objectives
The overall framework of Precision-Panc aims to accelerate stratified therapeutic development though co-ordination, data sharing and aligned decision-making. This UK-wide Master Protocol will enable the screening and molecular profiling of patients with pancreatic cancer, embedded within the standard diagnostic pathway to subsequent enrolment in available Pancreatic canceR Individualised Multi-arm Umbrella Study (PRIMUS) studies. PRIMUS is the set of clinical trials where patients may be recruited to the most suitable treatment studies based on their molecular phenotype and/or integrated with biomarker discovery and validation approaches. We aim to create a patient-focused environment where attractive trial options are offered to as many patients and their treating clinicians as possible. The aim is to identify the right trial for the patient, rather than current approaches where we search for patients for a specific trial. By offering a range of attractive options for patients and clinicians, we envisage significant increases in recruitment. In addition, Precision-Panc will also provide a platform for drug development in partnership with industry, by screening and identifying subgroup of patients with candidate biomarker of therapeutic responsiveness.

The outcomes of the patients will be recorded on the Master Protocol or the PRIMUS studies. Precision-Panc Master Protocol will serve not only as a molecular profiling platform for PRIMUS clinical trials, but also a translational research platform. The molecular profiling data generated along with the outcome data will be essential in the delineation of molecular mechanisms important in the pathophysiology of pancreatic cancer. This in turn will provide significant opportunities to understand the molecular pathology of pancreatic cancer better, and to identify candidate biomarkers for available therapeutic options and define therapeutic targets for novel drug development.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 1, 27/09/2017, ref: 17/WS/0147

Study design
Interventional non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Pancreatic Cancer

Interventions
Patients with either suspected or confirmed pancreatic cancer are approached to take part in the study and given the Precision Panc Screening PIS. Participants are given time to consider trial participation and if they are willing to take part in the study they are screened onto the study. If the patient has suspected pancreatic cancer and are having a standard of care diagnostic biopsy, extra cores are taken at that time for the Precision Panc study. If pancreatic ductal adenocarcinoma is confirmed the patient are then given the registration PIS/consent which allows for molecular profiling to take place on the extra tissue taken for research. If the patient already has a diagnosis of pancreatic ductal adenocarcinoma they are asked to undergo and additional research biopsy for the study. All participants are also asked to provide a blood sample for research. The tissue (either the extra diagnostic tissue or the research biopsy) and blood sample are sent to Glasgow for molecular profiling and if enough tissue is available for profiling they may be eligible for an open PRIMUS study.

Intervention Type
Procedure/Surgery

Primary outcome measure
To establish a mechanism and framework to recruit and screen patients with pancreatic cancer to perform molecular profiling, evaluation of circulating biomarkers and allow enrolment to Precision Panc PRIMUS studies. This will be measured by the number of patients screened and

registered to the study and the number of patients where a molecular profile is obtained. The number of patients registered to Precision Panc who then go onto a PRIMUS study will also be measured

Secondary outcome measures
1. To assess the overall survival (OS) in patients enrolled in Precision-Panc and relate this to molecular profile information
2. To assess the safety of obtaining tumour biopsies suitable for molecular profiling within a standard patient treatment pathway
3. To establish a central repository of molecular profiles with accompanying phenotypic data and accompanying biospecimens for further translational research
4. To establish a dynamic platform for evaluation of circulating biomarkers to subsequently inform design of subsequent clinical studies

Overall study start date
01/04/2017

Completion date
30/03/2022

Eligibility

Key inclusion criteria
1. Adult patients (age >16 years)
2. With either:
2.1. Presence of a hypodense pancreatic mass highly suspicious of primary pancreatic cancer with or without distant metastasis as assessed by a Pancreatic Multi-Disciplinary Team (MDT) or
2.2. Histologically or cytologically confirmed pancreatic ductal adenocarcinoma and its variants
3. Patient is willing and able to undergo tumour biopsy aimed at obtaining sufficient tissue for molecular profiling
4. Patient is deemed suitable to receive chemotherapy and/or radiotherapy, and/or surgery pending stage of disease at presentation
5. Signed informed consent for screening research tumour biopsy (Consent 1)
6. Signed informed consent for Precision-Panc Master Protocol molecular profiling (Consent 2)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2500-5000

Key exclusion criteria
There is no participant exclusion criteria.

Date of first enrolment
14/12/2017

Date of final enrolment
29/03/2022

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Study participating centre
UCLH
London
United Kingdom
NW1 2BU

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0QQ.

Study participating centre
Christie, Manchester
Manchester
United Kingdom
M20 4BX

Study participating centre
Weston Park
Sheffield
United Kingdom
S10 2SJ

Study participating centre
Bristol Oncology Centre
Bristol
United Kingdom
S10 2SJ

Study participating centre
Imperial College London
London
United Kingdom
SW7 2BX

Study participating centre
Nottingham University Healthcare Trust
Nottingham
United Kingdom
NG5 1PB

Study participating centre

Royal Free London Hospital
London
United Kingdom
NW3 2QG

Study participating centre
Ninewells Hospital
Dundee
United Kingdom
DD2 1UB

Study participating centre
St George's Hospital
London
United Kingdom
SW17 0QT

Study participating centre
Southampton University Hospital
Southampton
United Kingdom
SO16 6YD

Study participating centre
Queen Elizabeth Hospital Birmingham
Birmingham
United Kingdom
B15 2WB

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Study participating centre

Churchill Hospital
Oxford
United Kingdom
OX3 7LE

Study participating centre
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

Study participating centre
Poole Hospital
Poole
United Kingdom
BH15 2JB

Study participating centre
Freeman Hospital
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Royal Bournemouth Hospital
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Royal Albert Edward Infirmary
Wigan
United Kingdom
WN1 2NN

Study participating centre

Northern Ireland Cancer Centre
Belfast
United Kingdom
BT9 7JL

Study participating centre
Western General Infirmary
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Raigmore Hospital
Inverness
United Kingdom
IV2 3DZ

Study participating centre
Royal Liverpool Hospital
Liverpool
United Kingdom
L7 8XP

Study participating centre
Huddersfield Royal Infirmary
Huddersfield
United Kingdom
HD3 3EA

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
JB Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow

Scotland
United Kingdom
G12 OXH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
CRUK

Funder Name
Celgene

Alternative Name(s)
Celgene Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Judith Dixon at judith.dixon@glasgow.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		06/10/2017	02/04/2019	No	No
HRA research summary			28/06/2023	No	No