ISRCTN73852054 https://doi.org/10.1186/ISRCTN73852054

The impact of combined modality positron emission tomography with computerised tomography scanning (PET/CT) in the diagnosis and management of pancreatic cancer

Submission date 08/01/2015	**Recruitment status** No longer recruiting	✓ Retrospectively registered ? Protocol not yet added ? SAP not yet added ✓ Results added ? Raw data not yet added ✓ Study completed
Registration date 09/01/2015	**Overall study status** Completed	
Last Edited 24/05/2019	**Condition category** Cancer	

Plain English Summary
http://www.cancerresearchuk.org/about-cancer/trials/a-study-looking-pet-ct-scans-diagnose-cancer-pancreas-pet-panc

Contact information

Type(s)
Scientific

Contact name
Mr Robert Hanson

Contact details
University of Liverpool
Cancer Research UK Liverpool Cancer Trials Unit
200 London Road
Liverpool
United Kingdom
L3 9TA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
8166

Study information

Scientific Title
The impact of combined modality positron emission tomography with computerised tomography scanning (PET/CT) in the diagnosis and management of pancreatic cancer

Acronym
PET-PANC

Study hypothesis
The diagnosis of pancreatic cancer has improved with the use of multidetector CT, EUS, ERCP and additional use of MRI. There are, however, up to 10-20% of patients in whom an accurate diagnosis is difficult. This proportion is increasing due in part to larger numbers of asymptomatic patients undergoing cross sectional imaging. Invasive methods of diagnosis such as EUS +/- FNA can add to the accuracy of multidetector CT but may require an in-patient stay and have a recognised complication rate (1-2%). Currently patients with chronic pancreatitis, autoimmune pancreatitis, cystic lesions, small tumours <2cm, a bulky or diffusely enlarged pancreas on CT, a dilated pancreatic duct and no mass on CT, small volume metastatic disease and suspected recurrent disease (with no mass on CT) following resection are the most challenging patients to diagnose. A major goal of accurate diagnosis and staging is to avoid major pancreatic resection in patients who will not benefit. The use of a functional imaging technique such as PET/CT may add to staging of pancreatic cancer by diagnosing small volume metastatic disease and differentiate between benign and malignant lesions. Earlier diagnosis of pancreatic cancer will lead to a better prognosis for patients and PET/CT may be able to identify small volume disease or cancer arising in patients with chronic pancreatitis. There have been a number of studies to address diagnostic accuracy of PET/CT and two have looked at the issue of changes in management due to PET/CT. The main drawbacks of previous PET/CT studies tend to be that these are single centre studies with small numbers of patients and difficulties in standardising PET/CT protocol in pancreatic cancer. This prospective multicentre study aims to address these issues in a large group of patients to identify whether there is a role for PET/CT in addition to standard diagnostic work up in pancreatic cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - GM East (Cheshire), 18/03/2010, ref: 10/H1017/8

Study design
Non-randomised; Interventional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Topic: Cancer, Surgery; Subtopic: Upper Gastro-Intestinal Cancer, Surgery; Disease: Pancreas

Interventions
Combined modality positron emission tomography with computerised tomography scanning (PET/CT) in the diagnostic work up of patients with suspected pancreatic malignancy; Follow up length: 12 month(s).

Intervention Type
Procedure/Surgery

Primary outcome measure
The incremental diagnostic accuracy and impact of PET/CT to standard diagnostic work up; Timepoint(s): Outcome time point will be assessed after 12 Months of follow up

Secondary outcome measures
1. Determine cost effectiveness of addition of PET/CT in diagnosis, staging and management.; Timepoint(s): After 12 months follow up
2. Evaluate addition of PET/CT in differentiating pancreatic malignancy from chronic pancreatitis; Timepoint(s): After 12 months follow up
3. Evaluate change in diagnosis, staging and intended patient management through the addition of PET/CT; Timepoint(s): After 12 months follow up
4. Report the incremental diagnostic value of PET/CT for particular types of pancreatic tumour; Timepoint(s): After 12 months follow up
5. To identify which groups of patients would most benefit from PET/CT; Timepoint(s): After 12 months follow up

Overall study start date
06/01/2011

Overall study end date
26/04/2013

Eligibility

Participant inclusion criteria
1. Patients with suspected pancreatic malignancy as defined by one or more of:
1.1. Focal lesion in the pancreas/bulky pancreas/dilated pancreatic duct (+/- metastases) detected on Multidetector CT scan (+/- MRI/EUS/USS)
1.2. Jaundice due to distal obstruction of the common bile duct or ampulla (not due to calculi)

defined as serum bilirubin. 35 µmol/l
1.3. Serum CA19.9 value above 37KU/l
2. Able to attend for PET/CT scan
3. Able to undergo Multidetector CT scan
4. Able to attend for up to 12 months follow-up
5. Fully informed written consent given
6. Gender: Male & Female
7. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600; Description: Final sample size to be confirmed after interim analysis following recruitment of 200 patients.

Total final enrolment
589

Participant exclusion criteria
1. Patients younger than 18 years
2. Pregnancy
3. Patients with poorly controlled diabetes

Recruitment start date
06/01/2011

Recruitment end date
26/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Cancer Research UK Liverpool Cancer Trials Unit

200 London Road
Liverpool
United Kingdom
L3 9TA

Sponsor information

Organisation
University of Liverpool

Sponsor details
Foresight Centre
1-3 Brownlow Street
Liverpool
England
United Kingdom
L69 3GL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	01/02/2018		Yes	No