

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/05/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<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

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Contact details

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Additional identifiers

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 objectives

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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

Key secondary outcome(s)

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

Completion date

26/04/2013

Eligibility

Key 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 μ mol/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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

589

Key exclusion criteria

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

Date of first enrolment

06/01/2011

Date of final enrolment

26/04/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Liverpool

Cancer Research UK Liverpool Cancer Trials Unit

200 London Road

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Sponsor information

Organisation

University of Liverpool

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

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?
Results article	results	01/02/2018		Yes	No
Plain English results				No	Yes