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Evaluate - can magnetic resonance imaging (MRI) pick up early tumour spread in pancreatic cancer?

Submission date 27/09/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/11/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/06/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-whether-an-mri-scan-can-pick-up-early-spread-of-pancreatic-cancer

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Evaluation of multi-parametric magnetic resonance imaging for characterising lymph node status, peritoneal and liver metastasis in pancreatic cancer

Acronym
Evaluate

Study objectives
The overall study aim is to determine whether multi parametric MRI can identify lymph node, peritoneal and liver metastasis in patients referred for pancreaticoduodenectomy (surgery for pancreatic cancer), and to determine whether MRI can 'diagnose' resectability (i.e. identifies patients in whom the surgery should not go ahead).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Central Bristol Research Ethics Committee, 20/06/2016, re: 16/SW/0105

Study design
Single-centre proof-of-principle diagnostic accuracy study

Primary study design
Observational

Secondary study design
Diagnostic accuracy study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
All patients will attend the CRIC for a a multi-parametric MRI scan roughly 2 weeks before their surgery (index test); the MRI scan will not be reported and the images will not be made available to the care team. During surgery (usual care), a visual examination, intraoperative ultrasound and /or frozen section intraoperative biopsy with histopathology assessment will be carried out and the operating team will decide whether to resect or not (without inspecting the MRI scan).

The MRI will be assessed after the patients have had their surgical treatment (either the Whipple' s procedure or not) and the doctors reporting the scans will not know what treatment the patient has had or the results of any other tests. The doctors will attempt to identify from the MRI scan whether the cancer has spread to lymph nodes, the liver and abdomen, and make a decision based on the MRI as to whether the patient should have been referred for surgery or not. The decision to proceed with the surgery or not based on the MRI scan will then be compared with the same decision made by the surgeon at surgery.

Intervention Type
Other

Primary outcome measure
Proportion of patients correctly identified by MRI as being 'resectable' (no lymph node, peritoneal or liver metastases) as determined by sensitivity and positive predictive values (PPV). Data collected at surgery (whether resection for pancreatic cancer goes ahead or not) and the preoperative MRI scan (whether metastases are identified or not).

Secondary outcome measures
Data collected at surgery and the preoperative MRI scan:
1. Proportion of patients correctly identified by MRI to have lymph node, peritoneal or liver metastases. Position of 'pathological' lymph nodes on MRI is correlated with the final histology
2. Intra- and inter-observer reliability of MRI
3. Optimal combination of MRI parameters to detect metastasis
4. Safety of MRI in this patient population
5. Feasibility parameters (recruitment)
6. Resource use and costs for a preliminary economic evaluation, collected during the patient's hospital stay
7. Vital status of participants for 5 years after the last patient is recruited

Overall study start date
01/09/2016

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Patient ≥ 18 years
2. Confirmed or suspected pancreatic cancer referred for pancreaticoduodenectomy
3. Fit for general anaesthesia
4. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Prisoners and adults lacking capacity to consent
2. Patients undergoing distal or total pancreatectomy
3. Contraindications to MR (implanted electronic devices, metallic foreign bodies, claustrophobia, body weight >140 kg or waist perimeter exceeding manufacturer's recommendations and others according to manufacturer's recommendations and generally accepted guidelines)

Date of first enrolment
01/09/2016

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
United Kingdom

Study participating centre
University Hospitals Bristol NHS Foundation Trust
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Bristol Royal Infirmary
Upper Maudlin St
Bristol
England
United Kingdom
BS2 8HW

Sponsor type

Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/research-innovation

Funder(s)

Funder type
Charity

Funder Name
David Telling Charitable Trust

Results and Publications

Publication and dissemination plan
The study protocol can be made available on request (email: maria.pufulete@bristol.ac.uk). Planned publication of the study results in a high-impact peer-reviewed journal around June 2020.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
Anonymised individual patient data can be made available for secondary research (please contact maria.pufulete@bristol.ac.uk) when the study is complete and analysed (June 2020), conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No