

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

Contact name

Mr Jonathan Evans

Contact details

Level 7, Queens Building
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Single-centre proof-of-principle diagnostic accuracy study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pancreatic cancer

Interventions

All patients will attend the CRIC for 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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Funder(s)

Funder type

Charity

Funder Name

David Telling Charitable Trust

Results and Publications

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