ISRCTN84780767 https://doi.org/10.1186/ISRCTN84780767

Improving parenchymal phase imaging of the pancreas with multidetector CT using experience from dynamic contrast enhanced MR studies.

Submission date 29/09/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 15/05/2012	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nandita De Souza

Contact details
Clinical Magnetic Resonance
The Royal Marsden NHS Foundation Trust
Downs Road
Sutton
United Kingdom
SM2 5PT
+44 (0)20 8661 3289
nandita.desouza@icr.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0258161818

Study information

Scientific Title

Study objectives
To improve the diagnosis of pancreatic cancer by exploiting technology available on newer CT scanners to improve the enhancement of normal pancreatic tissue.

As of 15/05/2012, the anticipated end date for this trial has been updated from 18/04/2006 to 30 /06/2006.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

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

Interventions
Randomised test intervention vs standardised intervention, non-blinded (Phase III)

Intervention Type
Other

Phase

Phase III

Primary outcome measure
1. Absolute value of the Hounsfield attenuation in normal pancreatic tissue at pancreatic parenchymal phase.
2. Clinical radiologist's impression on the utility/benefit of mucosal enhancement of adjacent duodenum in aiding local staging.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/09/2005

Completion date
30/06/2006

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Age over 18 - pancreatic adenocarcinoma is unusual below this age and children are more sensitive to additional ionising radiation than adults
2. Stage III ovarian cancer or colorectal cancer
3. Routine attendance for contrast enhanced abdominal CT - no patients not otherwise having CT and contrast will be approached.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Severe local disease affecting pancreatic aorta/branches. This may introduce delays to the arrival of contrast due to compromise of arteries (SMA/Coeliac axis)
2. Major atherosclerotic disease of SMA/Coeliac axis - again, to avoid significant delay in contrast path distal to pancreatic aorta
3. Significant pancreatic resection - absence of normal pancreatic tissue will preclude our

numerical assessment of enhancement
4. Pre-existing pancreatic disease - cancer or pancreatitis.

Date of first enrolment
19/09/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Magnetic Resonance
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust

Funder Name
NHS R&D Support Funding

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