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Stereotactic body radiation therapy pre-operatively for borderline resectable pancreatic cancer

Submission date	Recruitment status	[X] Prospectively registered
18/03/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/03/2022	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-stereotactic-body-radiotherapy-before-surgery-for-pancreatic-cancer-sparc

Study website
https://www.oncology.ox.ac.uk/clinical-trials/oncology-clinical-trials-office-octo/completed-trials/SPARC

Contact information

Type(s)
Scientific

Contact name
Mrs Elizabeth Ward

Contact details
Department of Oncology
Oncology Clinical Trials Office (OCTO)
University of Oxford
Old Road Campus Research Building
Roosevelt Drive
Oxford
United Kingdom
OX3 7DQ

Type(s)
Public

Contact name

Ms Stephanie Levy

Contact details
Oncology Clinical Trials Office (OCTO)
Department of Oncology
University of Oxford
Old Road Campus
Roosevelt Drive
Oxford
United Kingdom
OX3 7DQ
+44 (0)1865 617084
stephanie.levy@oncology.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02308722

Secondary identifying numbers
OCTO_054; 18496

Study information

Scientific Title
A phase I trial of pre-operative, margin intensive, stereotactic body radiation therapy for pancreatic cancer

Acronym
SPARC: SBRT pre-operatively for pancreatic cancer

Study objectives
This study aims to test the safety and efficacy of pre-operative stereotactic body radiation therapy (SBRT), and to establish the maximum tolerated dose (MTD) of margin-intensive SBRT delivered pre-operatively in the surgical management of pancreatic cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Oxford B, ref: 15/SC/0059

Study design
Non-randomised; Interventional; Design type: Treatment

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Upper Gastro-Intestinal Cancer; Disease: Pancreas

Interventions
Current interventions as of 10/05/2018:
This is a single-arm prospective phase I dose escalation radiation study investigating 5-fraction stereotactic radiotherapy prior to planned surgical resection in borderline resectable or resectable pancreatic cancer. If we achieve the MTD then we will recruit up to 24 patients from 5 UK centres (Oxford, Leeds, Glasgow, Nottingham and Newcastle). Eligible patients will receive 5 fractions of stereotactic radiotherapy over 5-8 days, and surgery, if appropriate, will take place 5-6 weeks after radiotherapy. Patients will be on the study for approximately 36 weeks from registration on the study to the end of treatment visit (last protocol visit).

Previous interventions:
This is a single-arm prospective phase I dose escalation radiation study investigating 5-fraction stereotactic radiotherapy prior to planned surgical resection in borderline resectable pancreatic cancer.
If we achieve the MTD then we will recruit up to 24 patients from 3 UK centres (Oxford, Leeds and Glasgow). Eligible patients will receive 5 fractions of stereotactic radiotherapy over 5-8 days, and surgery will take place 5-6 weeks after radiotherapy. Patients will be on the study for approximately 36 weeks from registration on the study to the end of treatment visit (last protocol visit).

Intervention Type
Other

Phase
Phase I

Primary outcome measure
Current primary outcome measure as of 10/05/2018:
Maximum Tolerated Dose (MTD); Timepoint(s): 30 days post-surgery for patients proceeding to surgery or 3 months post SBRT for patients not proceeding to surgery.

Previous primary outcome measure:
Maximum Tolerated Dose (MTD); Timepoint(s): 30 days post-surgery

Secondary outcome measures
Current secondary outcome measures as of 10/05/2018:
1. Resection rates: Definitive resection rate. Timepoint(s) of evaluation of this end point - surgery
2. Resection margin status: R0/R1/R2 resection margin rates. Timepoint(s) of evaluation of this end point - pathological specimen evaluated at surgery
3. Response rates: Rate of pathological complete response. Timepoint(s) of evaluation of this end point - pathological specimen evaluation post operation
4. Late SBRT toxicity (>1 month to 6 months post-surgery or to 6 months post SBRT for patients not proceeding to surgery): Any Late GI AE/other AE > grade 2 CTCAE v4.03. Timepoint(s) of evaluation of this end point - post-surgery visits >1 month, 3 months and 6 months or 3 and 6 months post-SBRT for patients not proceeding to surgery
5. Efficacy and long term safety of SBRT delivered pre-operatively in the management of pancreatic cancer: Overall survival and progression free survival at 12 and 24 months post D1 SBRT. Timepoint(s) of evaluation of this end point -12 and 24m FU
6. To investigate if a relationship between imaging and pathology can be established: Differences between R0 as predicted by CT + MRI + PET pre-SBRT, post-SBRT and pathology findings. Timepoint(s) of evaluation of this end point - post-surgery
7. To explore possible immune-related responses to SBRT in pancreatic cancer: Changes in levels of interferon-related RNA and cytological markers of the innate and adaptive immune response before and during SBRT in pancreatic cancer. Timepoint(s) of evaluation of this end point - before, during and after SBRT

Previous secondary outcome measures:
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Overall study start date
01/11/2014

Completion date
01/03/2019

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 10/05/2018:
1. Borderline resectable localised tumour of the pancreatic head/uncinate process/body as per NCCN Guidelines (tumours of the tail of pancreas are not eligible for inclusion) or operable tumour in contact with or operable tumour in contact with, as defined by CT +/MRI +/PET criteria within 28+/7 days prior to trial entry de novo or following chemotherapy.
2. Histologically proven pancreatic ductal adenocarcinoma or cytological proven pancreatic malignancy
3. Able to undergo biliary drainage using a stent
4. Deemed fit and suitable for surgical resection
5. No overt metastases or uncertain status with investigations suspicious of possible metastatic disease (e.g. small equivocal pulmonary nodule(s)).
6. Male or female, Age = 16 years
7. Life expectancy of at least 6 months
7. ECOG performance status 0-1
8. The patient is willing and able to comply with the protocol for the duration of the study, and scheduled followup visits and examinations
9. Written (signed and dated) informed consent and be capable of cooperating with protocol
10. Haematological and biochemical indices within given ranges

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10. Haematological and biochemical indices within given ranges

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Total final enrolment

Key exclusion criteria
Current participant exclusion criteria as of 10/05/2018:
1. Definite metastatic disease or local disease that cannot be encompassed in the SBRT field
2. History of previous or concurrent malignancy diagnoses for which the expected prognosis is likely to be worse than that of the current diagnosis of pancreatic cancer (excludes for example: e.g. localised prostate cancer, early colorectal cancer, early breast cancer, curatively-treated basal cell carcinoma of skin, carcinoma in situ of cervix; curatively treated cancer of other sites who are recurrence free for >3 years)
3. Serious medical or psychological condition precluding trial intervention
4. Previous upper abdominal or chest wall radiotherapy
5. Pregnancy. Pregnant or breastfeeding women or women of childbearing potential unless effective methods of contraception are used.
6. Any other psychological, social or medical condition, physical examination finding or laboratory abnormality that the Investigator considers makes the patient a poor trial candidate or could interfere with protocol compliance or the interpretation of the trial results.

Previous participant exclusion criteria:
1. Distant metastatic disease or local disease that cannot be encompassed in the SBRT field
2. History of previous or concurrent malignancy diagnoses (except curatively-treated basal cell carcinoma of skin, carcinoma in situ of cervix; curatively treated cancer of other sites who are recurrence free for ≥ 3 years)
3. Serious medical or psychological condition precluding neoadjuvant treatment and surgical resection
4. Previous upper abdominal or chest wall radiotherapy
5. Pregnancy. Pregnant or breastfeeding women or women of childbearing potential unless effective methods of contraception are used
6. Any other psychological, social or medical condition, physical examination finding or laboratory abnormality that the Investigator considers makes the patient a poor trial candidate or could interfere with protocol compliance or the interpretation of the trial results.

Date of first enrolment
17/04/2015

Date of final enrolment
22/03/2018

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre

Churchill Hospital
Oxford
United Kingdom
OX3 9DU

Study participating centre
The Beatson West of Scotland Cancer Centre
Glasgow
United Kingdom
G12 0YN

Study participating centre
Leeds Cancer Centre
Leeds
United Kingdom
LS9 7TF

Study participating centre
Nottingham University Hospitals
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Freeman Hospital
Newcastle
United Kingdom
NE7 7DN

Sponsor information

Organisation
University of Oxford

Sponsor details
c/o Ms Heather House
University of Oxford Clinical Trials and Research Governance Team
Joint Research Office Block 60
Churchill Hospital

Oxford
England
United Kingdom
OX3 7LE

Sponsor type
University/education

Website
https://www.admin.ox.ac.uk/researchsupport/ctrg/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Data from all sites will be analysed together and published as soon as possible. Individual participating PIs may not publish data concerning their participants which are directly relevant to questions posed by the trial until the TMG has published its report. The TMG will form the basis of the writing committee and advise on the nature of publications, subject to the Sponsor's requirements.

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/09/2016		Yes	No
Abstract results	abstract	01/02/2018		No	No
Results article	results	01/02/2021	29/09/2021	Yes	No
Plain English results		01/03/2022	02/03/2022	No	Yes
HRA research summary			28/06/2023	No	No