ISRCTN96169987 https://doi.org/10.1186/ISRCTN96169987

Selective Chemoradiation in Advanced LOcalised Pancreatic cancer

Submission date 08/04/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/05/2008	**Overall study status** Completed	
Last Edited 14/02/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-of-chemotherapy-followed-by-chemoradiotherapy-for-locally-advanced-pancreatic-cancer

Contact information

Type(s)
Scientific

Contact name
Dr Somnath Mukherjee

Contact details
Velindre NHS Trust
Velindre Road
Whitchurch
Cardiff
United Kingdom
CF14 2TL
+44 (0)2920 196184
Somnath.mukherjee@velindre-tr.nhs.wales.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2008-001394-15

ClinicalTrials.gov (NCT)
NCT01032057

Protocol serial number
Protocol no: WCTU012; Sponsorship no: SPON 415-07; EudraCT: 2008-001394-15

Study information

Scientific Title
A multi-centre randomised phase II study of induction chemotherapy followed by gemcitabine or capecitabine based chemoradiotherapy (CRT) for locally advanced non-metastatic pancreatic cancer

Acronym
SCALOP

Study objectives
Pancreatic cancer is the tenth most common cancer in the UK with nearly 7,000 patients being diagnosed in UK each year and mortality parallels its incidence indicating that an effective treatment is required. Localised inoperable cancer accounts for 30 - 40% of advanced disease and its optimal management is unclear. Chemotherapy alone is the predominant modality in the UK whilst CRT is the treatment of choice in the USA. It has been reported that patients receiving either modality have a median survival of around 10 months.

Gemcitabine is the established monotherapy for pancreatic cancer; its combination with erlotinib and capecitabine have produced small improvements in median survival of 0.5 and 1.4 months respectively. The rationale for additional loco-regional therapy includes prolongation of local control and downstaging of inoperable disease, both of which may improve survival. Advancement in radiation technique has minimised radiation toxicity and combined with improved patient care makes CRT a feasible option. A national survey through the pancreatic sub-group of ACORRN (Academic Clinical Oncology, Radiotherapy and Radiobiology Network) has shown that the use of CRT is fragmented across the UK with no consensus guidelines.

The SCALP phase II study is a feasibility study which attempts to evaluate the activity, safety and feasibility of two chemoradiation treatment in the management of locally advanced non-metastatic pancreatic cancer (LANPC). If either is found to be active, safe and feasible to use it may be considered as experimental arm(s) of a future phase III trial. Also it will attempt to define an acceptable CRT strategy in UK and to demonstrate that high quality Radiotherapy (RT) with central Quality Assurance (QA) can be delivered. We hope to conclude as to whether or not there is sufficient evidence to warrant further investigation of one or both of the CRT regimes in a future phase III trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Protocol approval is being sought from a Multi-Centre Research Ethics Committee (MREC). Each participating centre will be approved through a Regional Ethics Committee (REC) prior to patient recruitment.

Study design
Multi-centre phase II randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Localised advanced non-metastatic pancreatic cancer (LANPC)

Interventions
Patients will be recruited over a period of approximately 24 months. Patients satisfying inclusion and exclusion criteria will receive three cycles (12 weeks) of GEMCAP chemotherapy (each four-week cycle consists of gemcitabine 1000 mg/m^2 weekly for three weeks out of four and capecitabine 830 mg/m^2 twice daily [bd] daily for 21 days). If restaging computed tomography (CT) scan at 12 weeks confirms stable or responding disease encompassable in a radiation field, patients will be randomised to receive a CRT regimen consisting of a fourth cycle of GEMCAP (for three weeks) as above and either:
1. 50.4 Gy in 28 fractions over 5.5 weeks (1.8 Gy per fraction, Monday to Friday) and gemcitabine 300 mg/m^2 intraveous (IV) weekly for the duration of radiotherapy (RT), or
2. 50.4 Gy in 28 fractions over 5.5 weeks (1.8 Gy per fraction, Monday to Friday) and capecitabine 830 mg/m^2 bd (Monday to Friday) for the duration of RT

Radiotherapy will be planned conformally using single phase, three to four coplanar beams, using 6 - 10 MV photons, treating all fields daily Monday to Friday. Those who fail on chemotherapy at 12 weeks will be treated and followed up according to clinician's choice, but they will be followed up and data on treatment and death will be collected.

Total treatment duration is 22 weeks from screening until follow up; patients will be followed up until week 52.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Gemcitabine, capecitabine

Primary outcome(s)
In each arm of the trial: nine-month (from registration) progression-free survival, defined according to the RECIST (Response Evaluation Criteria in Solid Tumours) criteria

Key secondary outcome(s))
In each arm of the trial:
1. Toxicity, during and after treatment using National Cancer Institute Common Terminology Criteria for Adverse Events version three (NCI CTCAE v 3.0). Toxicity will be measured at baseline, weeks 5, 9, 13 (i.e. at the end of each GEMCAP cycle - prior to CRT), 17, 18, 19, 20, 21, 22 (during CRT), 23, 26, 39 and 52 (follow-up). Also, serious adverse events (SAEs) will be collected in real time.
2. Quality of life, measured at baseline, week 17, 23, 26, 39 and 52
3. Overall 12-month survival and time from registration to death by any cause. Those still alive will be censored at date last seen.
4. Objective disease response (based on RECIST criteria)

5. Progression-free survival (time to event). Time from registration to any progression (based on RECIST criteria) and/or death. Those progression-free and alive will be censored at date last seen.
6. Radiotherapy quality assurance (RT QA); planning will be between weeks 13 - 16, planned assessment will be during week 17
7. Tumour marker CA19-9, measured at baseline, weeks 17, 39 and 52

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Informed consent
2. Aged greater than or equal to 18 years, either sex
3. Histologically or cytologically confirmed inoperable (or medically unfit for surgery) adenocarcinoma of the pancreas
4. Chosen for non-surgical therapy by a specialised Multi-Disciplinary Team
5. World Health Organization (WHO) performance status 0 - 2
6. Neutrophils greater than or equal to 1.5 x 10^9/L, platelets greater than or equal to 100 x 10^9/L and haemoglobin greater than or equal to 10 g/dL
7. Adequate liver function tests:
7.1. Serum bilirubin less than 35 µmol/l. In patients who have had a recent biliary drain and whose bilirubin is descending, a value of less than or equal to 50 µmol/L is acceptable.
7.2. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) less than or equal to 2.5 x upper limit of normal (ULN)
7.3. Alkaline phosphatase less than or equal to 5 x ULN
8. Adequate renal function (glomerular filtration rate [GFR] greater than 50 ml/min Cockcroft and Gault)
9. Women and men of child-bearing potential should agree to use an adequate contraception method, which must be continued for three months after completion of chemotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Women who are pregnant or breast feeding
2. Any evidence of severe uncontrolled systemic diseases including uncontrolled coronary artery disease

3. Any patient with myocardial infarction or stroke within the last six months
4. No previous malignancies in the preceding five years except for in situ cancer of the uterine cervix and adequately treated basal cell skin carcinoma and early stage malignancy
5. Renal abnormalities such as polycystic kidneys or hydronephrosis or ipsilateral single kidney
6. Previous radiotherapy to upper abdomen
7. Recurrent cancer following definitive pancreatic surgery

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Velindre NHS Trust
Cardiff
United Kingdom
CF14 2TL

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C28958/A9355) - funded by a grant from the Feasibility Study Committee (FSC)

Funder Name
The Wales Cancer Trials Unit (WCTU) is core funded by CRUK and WCTU core resources will be used to support this trial.

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	01/04/2013		Yes	No
Results article	results	15/11/2015		Yes	No
Results article	results	01/08/2016	14/02/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes