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ESPAC-5: European Study group for Pancreatic Cancer - Trial 5

Submission date 03/04/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 03/04/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 16/12/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-chemotherapy-or-chemoradiotherapy-before-surgery-for-pancreatic-cancer-espac-5f

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-003932-56

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16201

Study information

Scientific Title
ESPAC - 5: European Study Group for Pancreatic Cancer - Trial 5: four arm, prospective, multicentre, randomised feasibility trial of immediate surgery compared with neoadjuvant chemotherapies and neoadjuvant chemoradiotherapy

Acronym
ESPAC-5

Study objectives
ESPAC-5: a multi-centre, prospective, randomised, feasibility Phase II trial comparing neoadjuvant therapy to immediate surgical exploration in patients with borderline resectable pancreatic cancer. The aim of this study will be to compare neoadjuvant chemotherapy (GemCap or FOLFIRINOX) or chemoradiotherapy with immediate surgery. All patients who undergo resection will also receive adjuvant chemotherapy as standard.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Haydock, 18/03/2014, ref: 14/NW/0036

Study design
Randomised; Interventional; Design type: Process of Care, Screening, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information sheet will be available online shortly. In the meantime please contact Karen Scott on 0151 795 5269 or email k.billington@liv.ac.uk to request a copy

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

Interventions
If eligible for the study patients will be randomised onto one of the following arms.

Arm A (control): Surgery. Eligible patients will undergo surgical exploration for resection within two weeks of randomisation. Following recovery from successful resection (up to 12 weeks) patients will undergo standard adjuvant chemotherapy either gemcitabine or 5-fluorouracil for six cycles ie. 24 weeks. If patients do not undergo successful resection then following recovery from surgery, further therapy will be as physicians choice. Patients will be followed up for 12 months after randomisation.

Arm B: GEMCAP. Within two weeks of randomisation, eligible patients will commence neoadjuvant Gemcitabine, 1000mg/m2 iv infusion over 30 mins, once a week for 3 of 4 weeks and capecitabine 830mg/m2 BD PO for 21 /28d, (one cycle) for 2 cycles i.e. 8 weeks . Four to six weeks after completion chemotherapy patients will undergo staging CT scan. If there has been no progression patients will then undergo surgical exploration within two weeks as for Arm A.

Arm C: FOLFIRINOX - Within two weeks of randomisation, eligible patients will commence neoadjuvant Oxaliplatin 85mg/m2, Irinotecan 180mg/m2, Folinic acid 400mg/m2, 5-FU 2400mg /m2 46 hour infusion, repeated every 2 weeks for 4 cycles. Growth factor support may be administered at the investigators discretion. Four to six weeks after completion chemotherapy patients will undergo staging CT scan. If there has been no progression patients will then undergo surgical exploration within two weeks as for Arm A.

Arm D: CRT. Within two weeks of randomisation, eligible patients will commence neoadjuvant CRT delivering a total dose of 50.4Gy in 28 daily fractions over 5 1/2 weeks (1.8Gy/#fraction Mon to Fri) with Capecitabine 830mg/m2 BD PO (Mon to Fri) throughout radiotherapy. Centres would be required to choose to use IMRT (preferred) or 3D conformal RT for all their patients. Four to six weeks after completion CRT patients will undergo staging CT scan. If there has been no progression patients will then undergo surgical exploration within two weeks as for Arm A.

Patients will be followed up for 12 months after randomisation.

Intervention Type
Mixed

Primary outcome measure
1. Recruitment rate
Recruitment rate will be measured by the proportion of centres that successfully engage in the study and by the overall recruitment. Centres will be classified as successfully engaged if the study has opened in a timely fashion and if they are achieving over 50% of the recruitment and randomisation rate estimated for their centre. The overall recruitment rate will be deemed successful if at least 80% of the centres have fully engaged in the study and the target rate has been achieved (100 patients in 24 months).

2. Resection rate
An overall resection rate will be measured using the total number of patients at baseline. A second resection rate will also be measured using only the patients who undergo explorative surgery. R1 and R0 resection margins will be used when measuring the resection rate R2 resection margins will be excluded.

Secondary outcome measures
Not provided at time of registration

Overall study start date

01/04/2014

Completion date
30/01/2021

Eligibility

Key inclusion criteria
1. Borderline resectable mass in the pancreatic head as defined by CT criteria
2. Histologically or cytologically proven pancreatic ductal adenocarcinoma (including variants)
3. Able to undergo biliary drainage using a fully covered self expanding metal stent
4. Age >= 18 years
5. WHO performance status 0, 1
6. Platelets >100 x 109/l; WBC > 3 x 109/l; neutrophils > 1.5 x 109/l
7. Serum bilirubin =1.5 ULN
8. Calculated creatinine clearance > 50ml/min
9. Able to comply with protocol requirements and deemed fit for surgical resection, chemotherapy and radiotherapy.
10. Written informed consent; Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 85

Total final enrolment
90

Key exclusion criteria
1. Distant metastatic disease
2. History of previous or concurrent malignancy diagnoses (except curatively-treated basal cell carcinoma of skin, carcinoma in situ of cervix)
3. Serious medical or psychological condition precluding neoadjuvant treatment and surgical resection
4. Previous chemotherapy or chemoradiotherapy
5. Pregnancy
6. WHO performance status 24
7. New York Heart Association Classification Grade III or IV
8. Patients with known malabsorption

Date of first enrolment
26/08/2014

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK Liverpool Cancer Trials Unit
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Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (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
Not provided at time of registration

Intention to publish date
01/04/2021

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?
Basic results		12/02/2022	20/05/2022	No	No
Results article		12/12/2022	16/12/2022	Yes	No
HRA research summary			28/06/2023	No	No