

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

<b>Submission date</b> 03/04/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/12/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2013-003932-56

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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/m<sup>2</sup> iv infusion over 30 mins, once a week for 3 of 4 weeks and capecitabine 830mg/m<sup>2</sup> 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/m<sup>2</sup>, Irinotecan 180mg/m<sup>2</sup>, Folinic acid 400mg/m<sup>2</sup>, 5-FU 2400mg

/m<sup>2</sup> 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/m<sup>2</sup> 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(s)**

### **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.

## **Key secondary outcome(s)**

Not provided at time of registration

## **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  $\geq$  18 years
5. WHO performance status 0, 1
6. Platelets  $>100 \times 10^9/l$ ; WBC  $> 3 \times 10^9/l$ ; neutrophils  $> 1.5 \times 10^9/l$
7. Serum bilirubin  $\leq 1.5$  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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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 2-4
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**

United Kingdom

England

### **Study participating centre**

**Cancer Research UK Liverpool Cancer Trials Unit**  
Liverpool  
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## Sponsor information

### Organisation

University of Liverpool (UK)

### 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, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Results article</a>	12/12/2022	16/12/2022	Yes	No
<a href="#">Basic results</a>	12/02/2022	20/05/2022	No	No
<a href="#">HRA research summary</a>		28/06/2023	No	No