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

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

# 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/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(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 >= 18 years
- 5. WHO performance status 0, 1
- 6. Platelets >100 x 109/l; WBC >  $3 \times 109/l$ ; neutrophils >  $1.5 \times 109/l$
- 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

# 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 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

United Kingdom

England

#### Study participating centre

# Cancer Research UK Liverpool Cancer Trials Unit

Liverpool United Kingdom L69 3GL

# 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?

Results article		12/12/2022	16/12/2022 Yes	No
Basic results		12/02/2022	20/05/2022 No	No
HRA research summary			28/06/2023 No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes