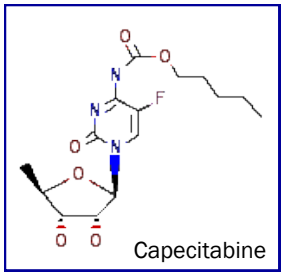
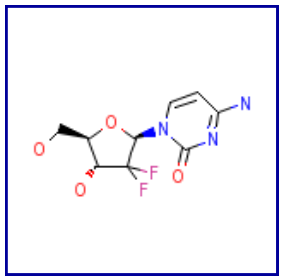
## ESPAC-4 Trial

The study is a two arm open-label, phase III, multi-centre, randomised, control trial.



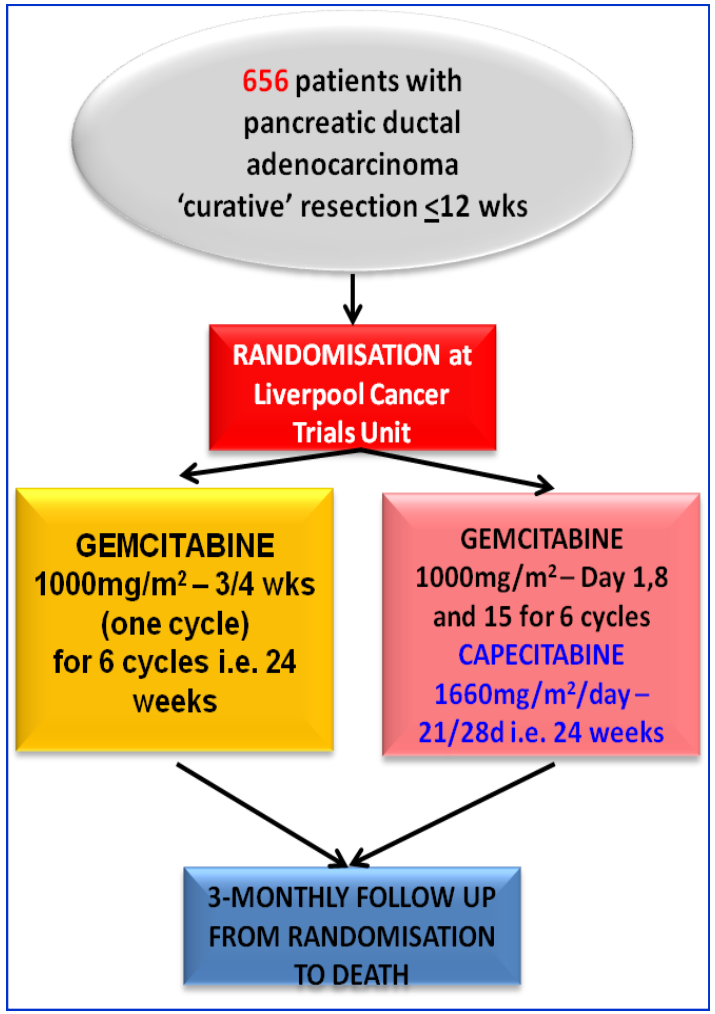



The aim of this trial is to compare survival following resection and either adjuvant **gemcitabine** plus **capecitabine** or **gemcitabine** alone in patients with pancreatic ductal adenocarcinoma.

## Treatment

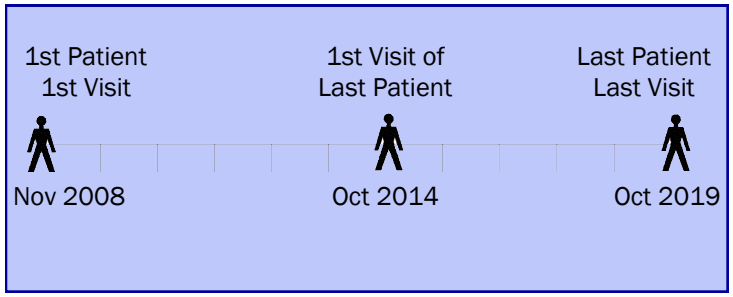
**Arm 1 – Gemcitabine alone**
Gemcitabine 1000mg/m$^2$ is given as an i.v. infusion over 30 minutes, the lyophilized powder being diluted in normal saline, will be administered once a week for three weeks out of every four weeks (one cycle) for six cycles i.e. 24 weeks.

**Arm 2 – Gemcitabine and Capecitabine Therapy**
Gemcitabine 1000mg/m$^2$ is given as an i.v. infusion over 30 minutes, the lyophilized powder being diluted in normal saline, This will be administered on day 1, 8 and 15. Capecitabine 1660mg/m$^2$/day in two divided doses administered orally for 21 days followed by 7 days' rest. Treatment will be repeated every 4 weeks for a total of 24 weeks.




## Time Schedule

Planned recruitment/finish dates for the trial




## Statistical Considerations

Patients with resected pancreatic ductal adeno-carcinoma will be randomised between the two chemotherapy arms.

656 patients will permit 90% power to detect at least a 10% absolute improvement in survival rate at 2 years in the combination group

The primary outcome measure is overall survival from randomisation.

The secondary outcome measures are:

1. Toxicity;
2. Quality of Life
3. Survival rate at 2 years;
4. Survival rates at 5 years

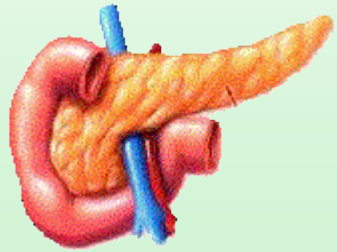
| | |
|---|---|
| Planned close date | 31/10/2014 |
| Target number of patients | 656 |
| Number of centres open | 62* |
| Total recruitment to date | 203* |
| Recruitment: UK | 162 |
| Recruitment: Sweden | 33 |
| Recruitment: France | 8 |

* As of 20/06/2011

ESPAC-4 recruited its first patient in November 2008 and hopes to recruit in Europe in a similar way to ESPAC-3(v2). Current recruitment stands at 203 patients.

# LCTU
## Liverpool Cancer Trials Unit

# ESPAC-4



## EUROPEAN STUDY GROUP FOR PANCREATIC CANCER—TRIAL 4.

## Combination versus single agent chemotherapy in resectable pancreatic cancer

EudraCT No.: 2007-004299-38

ISRCTN No.: ISRCTN96397434

## The LCTU

The Liverpool Cancer Trials Unit works closely with Cancer Research UK in the clinical research of new and existing products for the treatment of cancer, easing suffering and improving the quality of life for cancer patients.

## Further Information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For more information about pancreatic cancer or current trials running within the Liverpool Cancer Trials Unit, please email: lctu@liverpool.ac.uk

Or visit the ESPAC-4 website:

www.lctu.org.uk/espac4

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ESPAC-4 Leaflet Version: 4 Date: 20/06/2011

ESPAC-3(v2) opened in July 2000 and recruited 1583 patients in 159 centres across 17 countries and is the largest adjuvant trial ever conducted for pancreatic ductal adenocarcinoma.

The two year survival analysis of the ductal patient was presented at ASCO 2009 and showed no significant difference in survival between adjuvant 5FU/FA and adjuvant GEM.