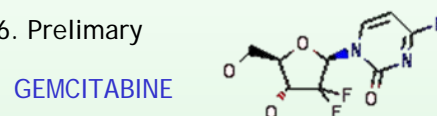
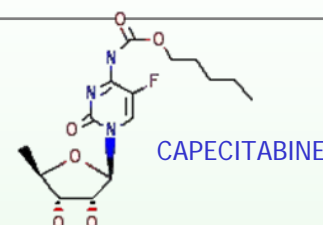


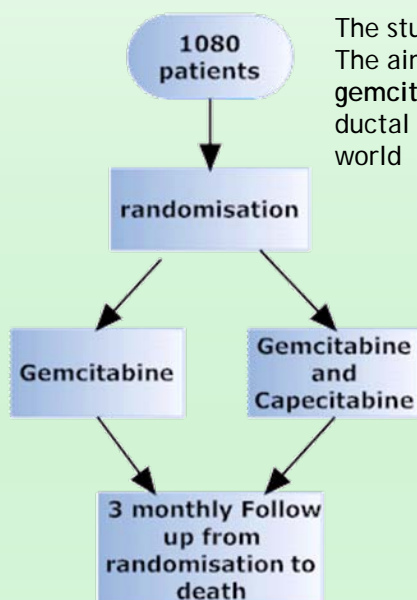


BACKGROUND

Pancreatic cancer is a major cause of cancer death in the western world ^{1,2}
 The long term survival rates following surgery vary between 10-15% ³
 The results from ESPAC-1 formed the basis of the ESPAC-3(v2) trial
 ESPAC-3(v2) compared survival following adjuvant gemcitabine versus 5-FU/FA in 1030 patients with ductal adenocarcinoma
 ESPAC-3(v2) closed for recruitment to this group of patients in December 2006. Preliminary survival analysis is expected once the event rate reaches 53%



STUDY DESIGN



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. ESPAC-4 hopes to recruit 1080 patients in sites around the world

Arm 1 - Gemcitabine alone

Gemcitabine 1000mg/m² is given as an i.v. infusion over 30 mins, 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/m² is given as an i.v. infusion over 30 mins, the lyophilized powder being diluted in normal saline, This will be administered on day 1, 8 and 15. Capecitabine 1660mg/m²/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.

ESPAC-3(v2) Update

TRIAL IS NOW CLOSED TO RECRUITMENT

Trial opened to recruitment 3 July 2000

154 approved centres (Ethics and regulatory) in 17 countries

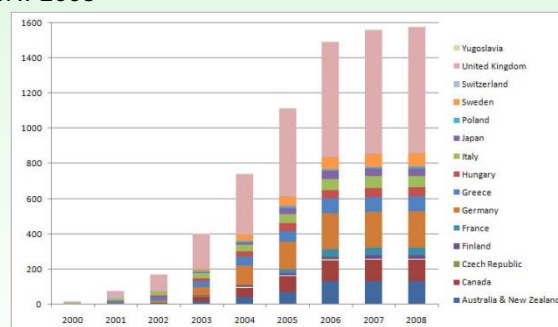
ESPAC-3(v2) is run to 90% power

Target of 1030 patients with ductal adenocarcinoma reached on 13 December 2006

Target of 300 patients with ampullary tumours reached on 16th April 2008

Analysis of ductal patients is scheduled for January 2009

TUMOUR TYPE	5FU	GEM	OBS	TOTAL TRT	OVERALL TOTAL
Ductal Adenocarcinoma	551	537	61	1088	1149
Ampullary	101	96	103	190	300
Other	42	48	41	90	131
					1580



FOR FURTHER DETAILS PLEASE CONTACT

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1. <http://www.iarc.fr/>

2. Jemal A, Siegel R, Ward E, et al. Cancer Statistics. CA Cancer J Clin 2006;56(2):106-130.

3. Alexakis N, Halloran C, Raraty M et al. Current standards of surgery for pancreatic cancer. Br J Surg 2004; 91:1410-27.