

# A phase III, multicentre randomised clinical trial comparing gemcitabine alone or in combination with capecitabine for the treatment of patients with advanced pancreatic cancer

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/single-or-combination-chemotherapy-for-patients-who-have-advanced-cancer-of-the-pancreas>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

ClinicalTrials.gov (NCT)

NCT00032175

## Study information

## Scientific Title

### Acronym

GEMCAP

### Study objectives

Does the addition of capecitabine to gemcitabine improve the survival or quality of life of patients with advanced pancreatic cancer?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration.

### Primary study design

Interventional

### Study design

Randomised controlled trial

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Advanced Pancreatic Cancer

### Interventions

Arm 1: Gemcitabine 1000 mg/m<sup>2</sup> weeks 1-7 followed by a 1-week rest. Treatment will then adopt a 28 day cycle where gemcitabine, 1000 mg/m<sup>2</sup>, will be given once weekly for 3 weeks followed by a 1-week rest.

Arm 2: Treatment follows a 28 day cycle. Gemcitabine, 1000 mg/m<sup>2</sup>, will be given weekly for 3 weeks followed by a 1-week rest. Capecitabine 830 mg/m<sup>2</sup> twice daily (total daily dose of 1660 mg/m<sup>2</sup>) will be administered orally for 21 days followed by 7 days rest.

### Intervention Type

Drug

### Phase

Phase III

### Drug/device/biological/vaccine name(s)

capecitabine, gemcitabine

### Primary outcome(s)

One-year survival.

### Key secondary outcome(s)

1. Quality of life
2. Median and 2-year survival rates
3. Toxicity
4. Objective response rates
5. Assessment of pain

**Completion date**

18/01/2005

## Eligibility

**Key inclusion criteria**

1. Age >18 years
2. Histologically or cytologically proven ductal adenocarcinoma or undifferentiated carcinoma of the pancreas
3. The presence of locally advanced or metastatic disease precluding curative surgical resection
4. Patients with macroscopic residual disease following resection confirmed by positive histology in post-resection tissue biopsies from the tumour bed (R2 resection) are also eligible
5. Unidimensionally measurable disease as assessed by computed tomography (CT) in accordance with the Response Evaluation Criteria in Solid Tumors (RECIST) guidelines. The only exception will be for patients with an R2 resection who will be evaluated for survival only.
6. No previous chemotherapy, radiotherapy or other investigational drug treatment for this indication
7. No previous preoperative or adjuvant chemotherapy, radiotherapy or other investigational drug treatment
8. World Health Organisation (WHO) performance status 0, 1 or 2
9. Adequate bone marrow function with platelets  $>100 \times 10^9/l$ ; white blood cells (WBC)  $>3 \times 10^9/l$ ; neutrophils  $>1.5 \times 10^9/l$  at the time of study entry
10. Serum bilirubin  $<35 \mu\text{mol/l}$
11. Serum creatinine  $<180 \mu\text{mol/l}$  and calculated creatinine clearance over 50 ml/min
12. No concurrent uncontrolled medical condition
13. No previous malignant disease other than non-melanotic skin cancer or carcinoma in situ of the uterine cervix
14. Life expectancy >3 months
15. Adequate contraceptive precautions if relevant
16. Informed written consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

## **Key exclusion criteria**

1. Medical or psychiatric conditions that compromise the patients ability to give informed consent
2. Intracerebral metastases or meningeal carcinomatosis
3. New York Heart Association classification Grade III or IV
4. Uncontrolled angina pectoris
5. Pregnancy or breast feeding
6. Impaired renal function with calculated creatinine clearance less than 50 ml/min
7. Previous investigational study drug
8. Known malabsorption syndromes
9. Patients with a known hypersensitivity to 5-FU or with a dihydropyrimidine dehydrogenase (DPD) deficiency

## **Date of first enrolment**

10/04/2002

## **Date of final enrolment**

18/01/2005

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

#### **Department of Medicine**

Sutton, Surrey

United Kingdom

SM2 5PT

## **Sponsor information**

### **Organisation**

Sponsor not defined (UK)

## **Funder(s)**

### **Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (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****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	20/11/2009		Yes	No