

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00032175

Secondary identifying numbers

N/A

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.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Advanced Pancreatic Cancer

Interventions

Arm 1: Gemcitabine 1000 mg/m² weeks 1-7 followed by a 1-week rest. Treatment will then adopt a 28 day cycle where gemcitabine, 1000 mg/m², 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/m², will be given weekly for 3 weeks followed by a 1-week rest. Capecitabine 830 mg/m² twice daily (total daily dose of 1660 mg/m²) 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 measure

One-year survival.

Secondary outcome measures

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

Overall study start date

10/04/2002

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 x 10⁹/l; white blood cells (WBC) >3 x 10⁹/l; neutrophils >1.5 x 10⁹/l at the time of study entry
10. Serum bilirubin <35 µmol/l

11. Serum creatinine <180 µmol/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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

508

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**

England

United Kingdom

Study participating centre
Department of Medicine
Sutton, Surrey
United Kingdom
SM2 5PT

Sponsor information

Organisation
Sponsor not defined (UK)

Sponsor details
-
-
United Kingdom
-

Sponsor type
Not defined

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/11/2009		Yes	No