ISRCTN11513444 https://doi.org/10.1186/ISRCTN11513444

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

Registration date
21/11/2005

Last Edited
09/05/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Prof David Cunningham

Contact details
Department of Medicine
Royal Marsden Hospital
Downs Road
Sutton, Surrey
United Kingdom
SM2 5PT

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/m^2 weeks 1-7 followed by a 1-week rest. Treatment will then adopt a 28 day cycle where gemcitabine, 1000 mg/m^2, 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^2, will be given weekly for 3 weeks followed by a 1-week rest. Capecitabine 830 mg/m^2 twice daily (total daily dose of 1660 mg/m^2) 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 10^9/l; white blood cells (WBC) >3 x 10^9/l; neutrophils >1.5 x 10^9/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