ISRCTN96397434 https://doi.org/10.1186/ISRCTN96397434

A trial comparing gemcitabine alone with gemcitabine and capecitabine together after surgery to remove cancer of the pancreas

Submission date
07/08/2007

Recruitment status
No longer recruiting

Registration date
08/02/2008

Overall study status
Completed

Last Edited
31/03/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-after-surgery-to-remove-cancer-of-the-pancreas-espac-4

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00058201

Clinical Trials Information System (CTIS)
2007-004299-38

Protocol serial number
ESPAC-4

Study information

Scientific Title
European Study Group for Pancreatic Cancer (ESPAC) - Trial 4: combination versus single agent adjuvant chemotherapy in resectable pancreatic cancer

Acronym
ESPAC-4

Study objectives
To investigate if combination chemotherapy (gemcitabine and capecitabine), when used as adjuvant therapy in patients following resection for pancreatic adenocarcinoma, improves survival over adjuvant therapy using gemcitabine alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Liverpool Adult Research Multi-centre Research Ethics Committee (MREC), 04/03/2008, ref: 08/H1005/1
2. MHRA acceptance also received on 20/02/2008, ref: 04196/0009/001

Primary study design
Interventional

Study design
Phase III international randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Resectable pancreatic cancer

Interventions
Gemcitabine and capecitabine versus gemcitabine alone

Gemcitabine administration:
1,000 mg/m^2 gemcitabine must be given as an intravenous infusion, the lyophilised powder being diluted in normal saline, over 30 minutes unless haematological toxicity occurs requiring dose adjustment. Administer on day 1, 8 and 15 (one cycle) for six cycles i.e. 24 weeks.

Capecitabine administration:
830 mg/m^2 capecitabine must be administered orally morning and evening daily (total daily dose of 1,660 mg/m^2) unless toxicity occurs requiring dose adjustment. The gemcitabine and capecitabine combination schedule used in this study originates from phase I data published by Schilsky et al. In this study the maximum tolerated dose was defined at gemcitabine 1 g/m^2 on days 1, 8 and 15, and capecitabine 1,660 mg/m^2/day given on days 1 - 21 every 28 days.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine, capecitabine

Primary outcome(s)
Current primary outcome measure as of 31/05/2011:
Length of survival. Duration of follow-up: 60 months from randomisation.

Previous primary outcome measure:
Length of survival. Duration of follow-up: 60 months from the date of surgery.

Key secondary outcome(s)
1. Toxicity. Duration of follow-up: 60 months from the date of surgery.
2. Quality of life, assessed by the European Organisation for Research and Treatment of Cancer, Quality of Life Questionnaires (EORTC C-30 QLQ) at baseline, 3, 6, 12, 16 and 24 months and annually thereafter up to 60 months
3. Two-year survival
4. Five-year survival
5. Relapse free survival (RFS). Duration of follow-up: 60 months from the date of surgery.

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Patients who have undergone complete macroscopic resection for ductal adenocarcinoma of the pancreas (R0 or R1 resection)
2. Completion of all pre-operative investigations
3. Histological confirmation of the primary diagnosis

4. Histological examination of all resection margins
5. No evidence of malignant ascites, liver metastasis, spread to other distant abdominal organs, peritoneal metastasis, spread to extra-abdominal organs - CT scan within 3 months prior to randomisation
6. A World Health Organization performance status less than 2
7. Fully recovered from the operation and fit to take part in the trial
8. Able to attend for administration of the adjuvant therapy
9. Able to attend for long-term follow-up
10. Life expectancy greater than 3 months
11. No previous or concurrent malignancy diagnoses (except curatively-treated basal cell carcinoma of skin, carcinoma in situ of cervix)
12. No serious medical or psychological condition precluding adjuvant treatment
13. Fully informed written consent given

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
730

Key exclusion criteria
1. Use of neo-adjuvant chemotherapy or other concomitant chemotherapy
2. Patients with pancreatic lymphoma
3. Macroscopically remaining tumour (R2 resection)
4. Patients with Tumor-Node-Metastasis (TNM) Stage IVb disease
5. Patients younger than 18 years
6. Pregnancy
7. New York Heart Association Classification Grade III or IV
8. Previous chemotherapy
9. All men or women of reproductive potential, unless using at least two contraceptive precautions, one of which must be a condom
10. Patients with known malabsorption

Date of first enrolment
13/10/2008

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United Kingdom

France

Germany

Sweden

Study participating centre
106 hospitals
United Kingdom
-

Sponsor information

Organisation
University of Liverpool and the Royal Liverpool and Broadgreen University Hospital NHS Trust (UK)

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) - funding the central co-ordination of the trial (the Liverpool Cancer Trials Unit) (grant ref: C245/A8968)

Funder Name
National Cancer Research Network (NCRN) nurse support at UK sites. Non-UK sites will be required to secure their own funding for participating in the trial.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/03/2017		Yes	No
Results article		05/12/2024	31/03/2025	Yes	No
Plain English results			26/10/2022	No	Yes