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Phase III adjuvant trial in pancreatic cancer comparing 5-Fluorouracil (5FU) and D-L-folinic acid versus gemcitabine versus no adjuvant treatment

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 28/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00058201

Protocol serial number
ESPAC-3

Study information

Scientific Title
Phase III adjuvant trial in pancreatic cancer comparing 5-Fluorouracil (5FU) and D-L-folinic acid versus gemcitabine versus no adjuvant treatment

Acronym
ESPAC-3

Study objectives
Not provided at time of registration

Please note that as of 03/09/09 the ethics and primary outcomes of this trial were updated. The end date of this trial was also extended from 01/12/2005 to 07/05/2008

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 03/09/09: Received from local medical ethics committee (MREC ref: 99/8/74)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pancreatic cancer

Interventions
1. 5-FU and Folinic Acid: Folinic Acid D-L form: 20 mg/m2 iv bolus injection followed by 5-FU: 425 mg/m2 iv bolus injection given on 5 consecutive days every 28 days for six cycles (24 weeks)
2. Gemcitabine: 1000 mg/m2 given as iv infusion over 30 min once a week for 3 of every 4 weeks for six cycles (24 weeks)
3. No adjuvant

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
5-Fluorouracil (5FU), D-L-folinic acid, gemcitabine

Primary outcome(s)

Added 03/09/09:
1. Survival at 2 and 5 years
2. Toxicity
3. Quality of life
4. Relapse free survival

Key secondary outcome(s))
Not provided at time of registration

Completion date
07/05/2008

Eligibility

Key inclusion criteria
1.1. Patients who have undergone complete macroscopic resection for ductal adenocarcinoma of the pancreas
1.2. Patients with other cancer may be included who have had complete macroscopic resection for unusual malignancies of the pancreas; cancer of the periampullary region; cancer of the intra-pancreatic bile duct; periampullary cancer of uncertain origin
2. Histological confirmation of the primary diagnosis
3. Histological examination of all resection margins
4. No evidence of malignant ascites, liver metastases, spread to other distant abdominal organs, peritoneal metastases, spread to extra-abdominal regions
5. A World Health Organisation (WHO) performance status ≤2
6. Fully recovered from surgery and fit to take part in the trial. Life expectancy of more than 3 months
7. Able to attend for administration of adjuvant therapy
8. Able to attend for long-term follow-up
9. No previous or concurrent malignancy diagnoses
10. No serious medical or psychological condition precluding adjuvant treatment
11. Fully informed written consent given

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
03/07/2000

Date of final enrolment
07/05/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

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

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/09/2010		Yes	No
Results article	results	11/07/2012		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	20/02/2014		Yes	No
Plain English results			28/10/2021	No	Yes