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Randomised trial of adjuvant therapy in operable pancreatic cancer

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 14/07/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ESPAC-1

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Hospital

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
Cancer of pancreas

Interventions
All patients undergo surgical resection followed by randomisation to one of four treatment arms:
1. Arm A: Radiotherapy, a split course of 40 Gy with a 2 week separation between each 20 Gy segment. Each 20 Gy segment to be given in 2 Gy fractions over 2 weeks. Chemotherapy with 5-fluorouracil to be administered intravenously on each of the first 3 days of each 20 Gy segment of radiotherapy.
2. Arm B: Systemic therapy with folinic acid followed by 5-fluorouracil to be given on 5 consecutive days every 28 days for six cycles
3. Arm C: Radiotherapy, a split course of 40 Gy with a 2 week separation between each 20 Gy segment. Each 20 Gy segment to be given in 2 Gy fractions over 2 weeks. Radiotherapy to be followed by systemic therapy with folinic acid and 5-fluorouracil to be given on 5 consecutive days every 28 days for six cycles.
4. Arm D: Control, no further treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Adjuvant therapy

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

Completion date
20/04/2000

Eligibility

Key inclusion criteria
1. Histologically proven adenocarcinoma of the pancreas, macroscopically resected. (Patients with pancreatic cystadenocarcinoma and endocrine tumours, tumours of the pancreas and tumours of the duodenum, ampulla of Vater and lower common bile duct are excluded).
2. No evidence of ascities, metastases to the liver, spread to other distant abdominal organs, peritoneal or omental seedlings, or distant metastases
3. Fully recovered from the operation, fit to take part in the trial and life expectancy of more than 3 months
4. No previous or concurrent malignancy diagnosed, except basal cell carcinoma of skin or carcinoma in situ of cervix
5. No serious medical or psychological condition precluding adjuvant treatment

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1995

Date of final enrolment
20/04/2000

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.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, 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	10/11/2001		Yes	No