ISRCTN21587955 https://doi.org/10.1186/ISRCTN21587955

Randomised trial of adjuvant therapy in operable pancreatic cancer

Submission date	Recruitment status	[_] Prospectively registered
01/07/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2014	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Not provided at time of registration

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex

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
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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/11/2001		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes