

Randomised trial of adjuvant therapy in operable pancreatic cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Primary study design

Interventional

Study design

Randomised controlled trial

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