Randomised trial of adjuvant therapy in operable pancreatic cancer

Submission date 01/07/2001	Recruitment status No longer recruiting	 Prospectively registered Protocol 	
Registration date	Overall study status	Statistical analysis plan	
01/07/2001	Completed	[X] 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 Dr - -

Contact details UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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 5fluorouracil 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

 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).
 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?
<u>Results article</u>	results	10/11/2001		Yes	No