# Randomised trial of adjuvant therapy in operable pancreatic cancer

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
01/07/2001		Protocol		
Registration date 01/07/2001	Overall study status Completed	Statistical analysis plan		
		[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

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 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

# 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

# Locations

# Countries of recruitment

England

**United Kingdom** 

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom

# Sponsor information

# Organisation

NW1 2DA

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, Cancer Research UK (CRUK), 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

# **Study outputs**

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