

A randomised trial of CF (infusional 5-fluorouracil and cisplatin) alone versus CF plus concurrent radiotherapy in patients with locally advanced pancreatic carcinoma

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/10/2019	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A randomised trial of CF (infusional 5-fluorouracil and cisplatin) alone versus CF plus concurrent radiotherapy in patients with locally advanced pancreatic carcinoma

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Pancreas cancer

Interventions

1. Regimen A: 5-fluorouracil, continuous infusion for 18 weeks, plus cisplatin repeated every 3 weeks for six cycles.

2. Regimen B: Cisplatin repeated every 3 weeks for four cycles plus 5-fluorouracil, continuous infusion for 12 weeks followed by continuous infusion for a further 6 weeks at a reduced dose. Radiotherapy 50 Gy in twenty-five fractions given over 5 weeks. Radiotherapy to commence on week 13 of chemotherapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cancer drugs

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1989

Completion date

11/11/1994

Eligibility

Key inclusion criteria

1. Histological evidence of locally advanced or unresectable pancreatic adenocarcinoma
2. Patients evaluable for response must have bidimensionally measurable disease as assessed by Computed Tomography (CT) scans
3. No prior chemotherapy or radiotherapy
4. Life expectancy of >3 months
5. Adequate bone marrow and renal function
6. World Health Organisation (WHO) performance status 0-2 at randomisation
7. No medical contraindications to treatment protocols

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

01/01/1989

Date of final enrolment

11/11/1994

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

Sponsor details

Downs Road

Sutton

England

United Kingdom

SM2 5PT

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Marsden Hospital (UK)

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