

A Randomised Study of continuous infusion 5-Fluorouracil (5FU) with or without bolus Mitomycin-C in Patients with Advanced Pancreatic Cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/08/2002	Overall study status Completed	☐ Protocol
Last Edited 07/06/2012	Condition category Cancer	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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

RMH E/C 1041

Study information

Scientific Title

Study objectives

Not provided at time of registration

As of 05/08/09 this trial was updated. All updates can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pancreatic cancer

Interventions

Two Arms:

1. Protracted venous infusion (PVI) 5FU 300 mg/m²/day over 24 weeks
2. PVI 5FU 300 mg/m²/day over 24 weeks MMC 7 mg/m² (total dose not to exceed 56 mg) four courses over 24 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-Fluorouracil (5FU), mitomycin-C

Primary outcome(s)

Added 05/08/09:

1. tumour response
2. survival
3. toxicity
4. quality of life (QoL)

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2000

Eligibility

Key inclusion criteria

Histological evidence of locally advanced or metastatic carcinoma of the pancreas not amenable to surgery or radiotherapy. Alternatively patients would have radiologically measurable evidence of locally advanced or metastatic carcinoma of the pancreas not amenable to surgery or radiotherapy, without histological evidence but with a carcinoembryonic antigen (CEA) above 50.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Royal Marsden Hospital NHS Foundation Trust (UK)

Results and Publications

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?
Results article	results	15/07/2002		Yes	No