

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

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/06/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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/m<sup>2</sup>/day over 24 weeks
2. PVI 5FU 300 mg/m<sup>2</sup>/day over 24 weeks MMC 7 mg/m<sup>2</sup> (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?
<a href="#">Results article</a>	results	15/07/2002		Yes	No