ISRCTN61961630 https://doi.org/10.1186/ISRCTN61961630

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 [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 07/06/2012	**Condition category** Cancer	

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

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

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
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 measure
Added 05/08/09:
1. tumour response
2. survival
3. toxicity
4. quality of life (QoL)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Final recruitment: 208 (added 05/08/09)

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
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
Research organisation

Funder Name
Royal Marsden Hospital NHS Foundation Trust (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/07/2002		Yes	No