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# A randomised study of continuous infusional 5-Fluorouracil (5FU) with or without mitomycin-C in patients with neuroendocrine tumours

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>27/06/2012 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
RMH E/N 1169

# Study information

### Scientific Title

### Study objectives
To compare the response rate and quality of life in patients having these regimens.

### 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
Neuroendocrine tumours

### Interventions
Two arms:
Regimen 1. Protracted venous infusion (PVI) 5FU 300 mg/m2/day over 24 weeks
Regimen 2. PVI 5FU 300 mg/m2/day over 24 weeks Mitomycin-C 7 mg/m2 (total dose must not 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
1. Response rate
2. Toxicity
3. Time to disease progression
4. Survival
5. Quality of life

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
12/09/1995

### Completion date
26/11/2003

## Eligibility

### Key inclusion criteria
1. Histological evidence of neuroendocrine tumours not amenable to surgery or radiotherapy
2. Patients evaluable for response must have bi-dimensionally measurable disease as assessed by chest X-ray or computed tomography (CT) scan
3. This disease must be outside previously irradiated areas

### 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
12/09/1995

### Date of final enrolment
26/11/2003

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Department of Medicine**
Sutton
United Kingdom
SM2 5PT

# 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

### Study outputs

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