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

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 27/06/2012	**Condition category** 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