

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
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/06/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

1. Response rate
2. Toxicity
3. Time to disease progression
4. Survival
5. Quality of life

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre**Department of Medicine**

Sutton

United Kingdom

SM2 5PT

Sponsor information**Organisation**

The Royal Marsden NHS Foundation Trust (UK)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Marsden Hospital (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