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A randomised study of continuous infusional 5-fluorouracil (5FU) with or without bolus mitomycin-C in patients with advanced oesophago-gastric 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 21/11/2012	**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

Protocol serial number
RMH E/C 1040

Study information

Scientific Title

Study objectives
Added 16/04/2009:
To compare protracted venous infusion (PVI) fluorouracil (5-FU) with PVI 5-FU plus mitomycin C (MMC) in patients with advanced oesophago-gastric cancer.

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)
Added 16/04/2009: The study was approved by the Local Research and Ethics Committee at each of the five participating centres.

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced oesophago-gastric cancer

Interventions
Two arms:
1. Protracted venous infusion (PVI) 5FU 300 mg/m^2/day over 24 weeks
2. PVI 5FU 300 mg/m^2/day over 24 weeks and mitomycin-C 7 mg/m^2 (total dose no more than 56 mg) four courses over 24 weeks

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
5-fluorouracil (5FU), mitomycin-C

Primary outcome(s)
Added 16/04/2009:
1. Tumour response, assessed by computed tomography (CT) scan before chemotherapy, 6-weekly during chemotherapy and 3-monthly thereafter until death or disease progression
2. Survival
3. Toxicity, evaluated on a weekly basis and graded according to the National Cancer Institute

Common Toxicity Criteria (NCI CTC)
4. Quality of life, assessed using European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaires before randomisation and every 12 weeks thereafter

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/03/2001

Eligibility

Key inclusion criteria
1. Histological evidence of metastatic carcinoma of the oesophagus or stomach
2. Histological evidence of locally advanced oesophageal or gastric carcinoma, not amenable to surgery or radiotherapy and for whom high dose chemotherapy or more intensive chemotherapy is not appropriate, normally around the age of 60

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Intra-cerebral metastases
2. History of other malignancy (apart from adequately treated non-melanotic skin cancer or carcinoma in situ of the uterine cervix)
3. Uncontrolled angina pectoris or clinically significant cardiac dysrhythmias
4. Pregnancy
5. Any psychological condition precluding informed consent

Date of first enrolment
01/07/1994

Date of final enrolment
31/03/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
GI and Lymphoma Units
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
The Royal Marsden 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?
Results article	results	01/10/2002		Yes	No