ISRCTN63374575 https://doi.org/10.1186/ISRCTN63374575

# A randomised study of continuous infusional 5-Fluorouracil (5FU) with or without bolus mitomycin-C in patients with carcinoma of unknown primary origin

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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>30/05/2012 | **Condition category**<br>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

**Protocol serial number**
RMH E/N 1042

## 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

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Carcinoma of unknown primary origin

## Interventions
1. Regimen 1. Protracted Venous Infusion (PVI) 5FU 300 mg/m/day over 24 weeks
2. Regimen 2. PVI 5FU 300 mg/m/day over 24 weeks Mitomycin-C 7 mg/m (total 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(s)
Added 05/08/09:
1. tumour response
2. survival
3. toxicity
4. quality of life (QoL)

## Key secondary outcome(s))
Not provided at time of registration

## Completion date

30/04/2001

# Eligibility

### Key inclusion criteria
1. Histological evidence of carcinoma of unknown primary site
2. Patients evaluable for response
3. Must have bi-dimensionally measurable disease as assessed by chest X-ray or Computed Tomography (CT) scan
4. 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
01/01/1995

### Date of final enrolment
30/04/2001

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

# Sponsor information

**Organisation**
The Royal Marsden NHS Foundation Trust (UK)

**ROR**
https://ror.org/0008wzh48

# Funder(s)

**Funder type**
Research organisation

**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 | 01/05/2003 | | Yes | No |