

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

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/05/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Added 05/08/09:

1. tumour response
2. survival
3. toxicity
4. quality of life (QoL)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1995

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Final recruitment:88 (added 05/08/09)

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

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

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

Research organisation

Funder Name

The Royal Marsden NHS Foundation Trust (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	01/05/2003		Yes	No