

A randomised study of continuous infusional 5-fluorouracil with or without bolus mitomycin-C in patients with advanced colorectal cancer

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

COMBAT COIRE

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval information required 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

Colon, Rectal cancer

Interventions

1. Regimen one: continuous infusion 5-fluorouracil. The infusion will be given for 12 weeks and for a further 12 weeks in responding patients or patients with stable disease.
2. Regimen two: continuous infusion 5-fluorouracil given as above plus mitomycin-C given every 6 weeks for two courses and to a total of four courses in responding patients or patients with stable disease.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-fluorouracil, 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

13/03/1995

Completion date

13/03/1996

Eligibility

Key inclusion criteria

1. Histological evidence of metastatic adenocarcinoma of the colon or rectum not amenable to surgery or radiotherapy
2. Patients evaluable for response must have bi-dimensionally measurable disease
3. Patients with no measurable disease
4. Adequate bone marrow function
5. Serum creatinine within normal range
6. Life expectancy of greater than 3 months
7. Eastern Cooperative Oncology Group (ECOG) performance status 0-2

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

200 (final: 98 active, 97 controls)

Key exclusion criteria

1. History of other malignant disease other than non melanotic skin cancer or carcinoma in situ of the cervix
2. Prior treatment with any cytotoxic agent except adjuvant chemotherapy completed more than 12 months from randomisation
3. Intracerebral metastases or meningeal carcinomatosis
4. Medical contraindications to treatment

Date of first enrolment

13/03/1995

Date of final enrolment

13/03/1996

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

Hospital/treatment centre

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	01/10/1997		Yes	No