ISRCTN27478455 https://doi.org/10.1186/ISRCTN27478455

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

Submission date	Recruitment status	[_] Prospectively registered
19/08/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/05/2012	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(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
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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
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
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	01/10/1997		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes