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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 30/05/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

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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