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# A Randomised Trial Comparing the Efficacy of Infusional 5-Fluorouracil (5-FU) to 5-FU plus Alpha Interferon in Patients with Unresectable Colorectal Cancer

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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>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/10/2012 | **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**
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

COLO 1

# Study information

### Scientific Title

### Study objectives
Not provided at time of registration

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Colon, Rectum

### Interventions
1. Regimen A: 5-fluorouracil, continuous intravenous infusion
2. Regimen B: 5-fluorouracil, continuous intravenous infusion, plus alpha-interferon five mega units given subcutaneously three times a week for the duration of 5-fluorouracil treatment

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
5-Fluorouracil Alpha Interferon

### Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2002

### Completion date
31/12/2002

## 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. No prior treatment with 5-fluorouracil or other cyctotoxic agent or interferon
5. Adequate bone marrow function
6. Life expectancy of greater than 3 months
7. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
8. No history of other malignant disease other than non melanotic skin cancer or carcinoma in situ of the cervix
9. No intracerebral metastases or meningeal carcinomatosis
10. No medical contraindications to treatment

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
Not provided at time of registration

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/01/2002

### Date of final enrolment
31/12/2002

## 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
Government

### Funder Name
Royal Marsden Hospital NHS 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