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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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 09/10/2012	**Condition category** Cancer	

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

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