

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
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 09/10/2012	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

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

Protocol serial number

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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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 cytotoxic 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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

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

Government

Funder Name

Royal Marsden Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration