ISRCTN42493631 https://doi.org/10.1186/ISRCTN42493631

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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
09/10/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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 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

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