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A Pilot Randomised Trial Comparing Short Course Infusional 5-Fluourouracil with 5-Fluorouracil and Leucovorin as Adjuvant Therapy for Resected Colorectal Carcinoma

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 21/11/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SAFFA

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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

Interventions
1. Regimen A: Continuous infusion of 5-fluorouracil over 12 weeks.
2. Regimen B: Folinic acid intravenous bolus injection, followed by 5-fluorouracil intravenous bolus injection given on 5 consecutive days and repeated every 28 days for six cycles

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cancer drugs

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2006

Eligibility

Key inclusion criteria

1. Histologically verified adenocarcinoma of colon or rectum, Dukes stages B or C
2. No evidence of residual local disease or metastatic disease as assessed at time of operation, clinical examination, and by ultrasound scanning
3. No past history of malignancy apart from non melanotic carcinoma of the skin or in-situ carcinoma of the cervix
4. No previous chemotherapy
5. Normal bone marrow, renal and liver function
6. Patients must be randomised within 10 weeks of surgery
7. 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
19/08/1993

Date of final enrolment
31/12/2006

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
Research organisation

Funder Name
Royal Marsden Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration