

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

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/11/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

19/08/1993

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

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

19/08/1993

Date of final enrolment

31/12/2006

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

Research organisation

Funder Name

Royal Marsden Hospital (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