

A pilot randomised trial comparing short course infusional 5-Fluorouracil (5FU) with 5FU + Leucovorin as adjuvant therapy for resected colorectal carcinoma

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/01/2016	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A pilot randomised trial comparing short course infusional 5-Fluorouracil (5FU) with 5FU + Leucovorin as adjuvant therapy for resected colorectal carcinoma

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)

Hospital

Study type(s)

Treatment

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

Colorectal carcinoma

Interventions

1. 5FU (Protracted venous infusion [PVI]) 12 weeks (300 mg/m²)
2. 5FU + Folinic Acid (NCCTG) (425 mg/m² + 20 mg/m²) every 28 days for six courses

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

5-fluorouracil, leucovorin

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

31/12/2003

Eligibility

Key inclusion criteria

1. Adenocarcinoma - Dukes stage B or C
2. No evidence of residual or metastatic disease assessed at surgery, clinically or radiologically

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

31/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
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
Hospital/treatment centre

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