

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	☐ Prospectively registered
Registration date 19/08/2002	Overall study status Completed	☐ Protocol
Last Edited 11/01/2016	Condition category Cancer	☐ 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

RMH E/C 920

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

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

31/12/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Hospital/treatment centre

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