

A randomised trial of adjuvant 5-fluorouracil, leucovorin and radiotherapy in colorectal adenocarcinoma

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/01/2016	Condition category Cancer	☐ 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

NICCO CRCI

Study information

Scientific Title

A randomised trial of adjuvant 5-fluorouracil, leucovorin and radiotherapy in colorectal adenocarcinoma

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

Colon, Rectal cancer

Interventions

COLON CANCER: Following surgery patients are randomised to one of two groups:

1. Group A: No adjuvant therapy
2. Group B: Adjuvant chemotherapy with 5-fluorouracil and folinic acid repeated every 14 days for eight courses.

RECTAL CANCER: Following surgery patients are randomised to one of two groups:

1. Group A: No adjuvant therapy
2. Group B: Radiotherapy 4400 cGy in 22 daily fractions plus adjuvant chemotherapy with 5-fluorouracil and folinic acid repeated every 14 days for eight courses. Radiotherapy to be given five days per week prior to or concurrent with chemotherapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-fluorouracil and folinic acid (leucovorin)

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/08/2003

Eligibility

Key inclusion criteria

1. Aged 18 to 80 years
2. World Health Organisation (WHO) performance status zero to two
3. Histological proof of colorectal adenocarcinoma
4. The entire colorectum must be visualised pre- or postoperatively to exclude synchronous carcinoma
5. Potentially curative surgery
6. Adjuvant treatment to be initiated within six weeks of surgery
7. Adequate bone marrow, renal and hepatic function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

No previous malignancy except carcinoma in situ of cervix or basal cell carcinoma of skin

Date of first enrolment

01/08/2002

Date of final enrolment

01/08/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Wyeth-Lederle Ltd (UK)

ROR

<https://ror.org/04x4v8p40>

Funder(s)

Funder type

Industry

Funder Name

Wyeth-Lederle Ltd (UK)

Funder Name

Friends Of Montgomery House (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration