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

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2002	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/01/2016	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2002

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

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Wyeth-Lederle Ltd (UK)

Sponsor details
Huntercombe Lane South
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Sponsor type
Industry

Website
http://www.wyeth.co.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

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