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Chemotherapy choices in advanced colorectal cancer - a randomised trial comparing two durations and three chemotherapy regimens in the palliative treatment of advanced colorectal cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 30/07/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CR06

Study information

Scientific Title

Study objectives
This trial aims to address two questions in the palliative treatment of patients with advanced colorectal cancer, namely:
1. Are the three chemotherapy regimens equivalent in terms of survival, and if so are there differences in the levels of quality of life (QoL) experienced by the patients?
2. In patients with stable or responding disease at 12 weeks, is there a survival benefit if chemotherapy is continued indefinitely, compared to a policy of stopping chemotherapy at 12 weeks, and what are the quality of life implications?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Patients with advanced colorectal cancer are randomised between three groups:
1. De Gramont bolus and infusion 5FU and folinic acid regimen
2. Lokich continuous infusion 5FU regimen
3. 'Tomudex' iv bolus.

After 12 weeks their status is reassessed and those patients with responding or stable disease are randomised to one of two groups:
1. STOP chemotherapy, retreating on progression if appropriate
2. CONTINUE chemotherapy, with 12-weekly review, until disease progression, or unacceptable toxicity

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
fluorouracil, leucovorin calcium, raltitrexed

Primary outcome(s)
Survival

Key secondary outcome(s)
Quality of life, palliation of symptoms, toxicity, psychological impact, functional status, social functioning, global quality of life, subsidiary response rate health economics acceptability of treatment to patients

Completion date
10/05/1999

Eligibility

Key inclusion criteria
First randomisation inclusion:
1. Histologically confirmed adenocarcinoma of the colon or rectum
2. Patients with either: locally advanced disease at presentation suitable only for palliative chemotherapy; metastatic disease at presentation suitable only for palliative chemotherapy; recurrent locally advanced or metastatic disease, now only suitable for palliative chemotherapy. If systemic chemotherapy was given previously this must have been 5-Flurouracil (5FU) based adjuvant therapy (eg QUASAR) and completed more than six months prior to trial entry. Disease not limited to a previously irradiated area.
3. Objectively or subjectively evaluable disease
4. Adequate bone marrow function
5. Adequate renal function with serum creatinine 1.25 x upper limit of normal and creatinine clearance more than 65 ml if serum creatinine exceeds upper limit of normal
6. World Health Organisation (WHO) performance status of 0 - 2, with life expectancy more than three months
7. Patient able and willing to complete QoL questionnaires

Second randomisation: All patients in the trial should be randomised to stop or continue chemotherapy after 12 weeks (see 'Exclusions' below for exceptions)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Exclusion for second randomisation:
1. Patients with progressive disease on clinical or radiological evidence (more than a 25%

increase in size of an existing lesion, or new lesions), or death
2. Patients who have stopped chemotherapy because of toxicity
3. Patient choice

Date of first enrolment
10/05/1996

Date of final enrolment
10/05/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/02/2003		Yes	No