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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

Registration date
06/04/2000

Overall study status
Completed

Last Edited
30/07/2009

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Dionne Cain

Contact details
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
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

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 measure
Survival

Secondary outcome measures
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

Overall study start date
10/05/1996

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

Age group
Adult

Sex
Both

Target number of participants
First randomisation = 905, second randomisation = 354

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
England

United Kingdom

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

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

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