

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/07/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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-Fluorouracil (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 $1.25 \times$ 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

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Sponsor information**Organisation**

Medical Research Council (MRC) (UK)

Sponsor details

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Sponsor type

Research council

Website

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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