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A randomised trial of intravenous versus intrahepatic arterial 5-Flurouracil (5-FU) and leucovorin for colorectal liver metastases

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 31/07/2009	**Condition category** Cancer	

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

ClinicalTrials.gov (NCT)
NCT00002692

Protocol serial number
CR05

Study information

Scientific Title

Study objectives
To compare the efficacy and safety of intravenous and intrahepatic arterial infusion of 5-FU and leucovorin.

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)
Not Specified

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

Interventions
Intrahepatic arterial infusion of 5-FU/leucovorin

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Survival time

Key secondary outcome(s))
Quality of life, objective tumour response, duration of response, toxicity.

Completion date
31/08/2000

Eligibility

Key inclusion criteria
1. Histologically confirmed adenocarcinoma of the colon or rectum, confined to the liver, and not amenable to surgery or found to be unresectable during surgery

2. No previous treatment with 5-FU with the exception of adjuvant therapy (eg AXIS or QUASAR studies) completed more than 12 months prior to study entry
3. Adequate bone marrow function with platelets more than 100 x 10 to the power of 9 per litre; White Blood Count (WBC) more than 3.0 x 10 to the power of 9 per litre and neutrophils more than 1.5 x 10 to the power of 9 per litre at the time of study entry
4. No concurrent uncontrolled medical illness (eg uncontrolled heart failure, angina, infection, etc)
5. Life expectancy more than 3 months
6. WHO performance status 0, 1 or 2
7. Bilirubin less than 50 micromoles per litre

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/12/1994

Date of final enrolment
31/08/2000

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, 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	01/02/2003		Yes	No