

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

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/07/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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  $100 \times 10^9$  per litre; White Blood Count (WBC) more than  $3.0 \times 10^9$  per litre and neutrophils more than  $1.5 \times 10^9$  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, 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?
<a href="#">Results article</a>	results	01/02/2003		Yes	No