

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

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

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 100×10^9 per litre; White Blood Count (WBC) more than 3.0×10^9 per litre and neutrophils more than 1.5×10^9 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?
Results article	results	01/02/2003		Yes	No