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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
06/04/2000		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/04/2000	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
31/07/2009	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Dionne Cain

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00002692

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Survival time

Secondary outcome measures

Quality of life, objective tumour response, duration of response, toxicity.

Overall study start date

16/12/1994

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 to the power of 9 per litre; White Blood Count (WBC) more than 3.0×10 to the power of 9 per litre and neutrophils more than 1.5×10 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

Age group

Not Specified

Sex

Not Specified

Target number of participants

290

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

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	01/02/2003		Yes	No