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Randomised phase III study of the local treatment of liver metastases by radiofrequency combined with chemotherapy versus chemotherapy alone in patients with unresectable colorectal liver metastases

Submission date 04/06/2003	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/07/2003	**Overall study status** Stopped	
Last Edited 23/04/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00043004

Protocol serial number
EORTC 40004

Study information

Scientific Title
Randomised phase III study of the local treatment of liver metastases by radiofrequency combined with chemotherapy versus chemotherapy alone in patients with unresectable colorectal liver metastases

Acronym
CLOCC

Study objectives
The liver is the common site of relapse in patients with colorectal cancer. Chemotherapy is the treatment of choice for patients where surgical removal of lesions is not possible. The outcome for patients with unresectable liver metastases treated with chemotherapy is poor; five year survival of less than 1% and median survival less than one year.

Tumour destruction using radio frequency may offer an improvement in outcome. The purpose of this trial is to treat patients who have inoperable metastases with chemotherapy or RadioFrequency Ablation (RFA) and chemotherapy. The chemotherapy schedule used will be a combination of 5-Fluorouracil (5FU), leucovorin and oxaliplatin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
LREC approval for UK sites

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Liver metastases in colorectal cancer

Interventions
Arm one: Radiofrequency ablation and chemotherapy
Arm two: Chemotherapy alone.

Radiofrequency:
1. Tumour ablative technique which can be combined with surgery
2. Imaging of procedure by ultrasound
3. During radiofrequency thermal heat injury leads to tissue coagulation

4. Effective in the local destruction of liver metastases
5. Suitable for lesions which are not totally resectable due to number or location and close to large blood vessels

Chemotherapy:
1. Oxaliplatin 85mg/m^2 day one only
2. Leucovorin 175mg/m^2 day one only
3. 5-Fluorouracil 400mg/m^2 bolus
4. 5FU 2400mg/m^2 at 46 hours intravenous infusion
5. Fortnightly for six months i.e. 12 courses

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
5-Fluorouracil (5FU), LeucoVorin (LV) and oxaliplatin.

Primary outcome(s)
To determine whether radiofrequency in combination with chemotherapy leads to superior overall survival compared to chemotherapy alone.

Key secondary outcome(s))
1. Progression free survival
2. Quality of Life
3. Health economics

Completion date
30/09/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients with unresectable colorectal liver metastases:
1. Resection of primary tumour
2. Unresectable liver metastases
3. No extrahepatic disease
4. Total number of metastatic deposits less than ten
5. Maximum diameter of lesions 4cm
6. Patient consent
7. Aged 18 to 80 years
8. Normal haematology and biochemistry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
119

Key exclusion criteria
1. World Health Organisation (WHO) status of more than or equal to one
2. Hepatic sufficiency (Bilirubin, Alkaline Phosphatase more than three times the Upper Limit of Normal [ULN])
3. Peripheral neuropathy Common Toxicity Criteria (CTC) grade more than or equal to one
4. Uncontrolled congestive heart failure, angina pectoris, hypertension or arrythmia
5. Any contraindication to the use of 5FU/LV/Oxaliplatin
6. Active infection
7. Pregnant or lactating women

Date of first enrolment
01/04/2003

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
CR UK and UCL Cancer Trials Centre
London
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Sponsor information

Organisation
Cancer Research UK

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (ref: C8374/A3488)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2012	23/04/2021	Yes	No
Abstract results				No	No
Abstract results		20/05/2008	23/04/2021	No	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes