

# Pre and post operative chemotherapy with oxaliplatin, 5-Fluorouracil (5 FU)/Leucovorin (LV) versus surgery alone in resectable liver metastases from colorectal origin

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/10/2013	<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**  
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**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00006479

## Secondary identifying numbers

EORTC/GITCCG 40983

# Study information

## Scientific Title

## Acronym

Not Applicable

## Study objectives

Not provided at time of registration

## 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

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Colon, rectum

## Interventions

1. Arm A: Oxaliplatin 85 mg/m<sup>2</sup> (day 1) 5-FU: 2000 mg/m<sup>2</sup>/cycle (days 1 and 2), Leucovorin: 200 mg/m<sup>2</sup> (day 1 and 2), every 2 weeks for 6 cycles before surgery and for 6 cycles following surgery.
2. Arm B: Surgery alone.

## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

oxaliplatin, 5-Fluorouracil (5 FU)/Leucovorin (LV)

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/2000

**Completion date**

02/07/2004

**Eligibility****Key inclusion criteria**

1. All potentially resectable liver metastases without detectable extra-hepatic tumour
2. Primary tumour resected or resectable
3. No previous chemotherapy with oxaliplatin

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Added May 2008: 363

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/11/2000

**Date of final enrolment**

02/07/2004

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**UKCCCR Register Co-ordinator**  
London  
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## **Sponsor information**

### **Organisation**

Cancer Research UK (CRUK) (UK)

### **Sponsor details**

PO Box 123  
Lincoln's Inn Fields  
London  
United Kingdom  
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kate.law@cancer.org.uk

### **Sponsor type**

Charity

### **Website**

<http://www.cancer.org.uk>

### **ROR**

<https://ror.org/054225q67>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Cancer Research UK

### **Alternative Name(s)**

CR\_UK, Cancer Research UK - London, CRUK

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Other non-profit organizations

### **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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/11/2013		Yes	No