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

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 29/10/2013	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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/m2 (day 1) 5-FU: 2000 mg/m2/cycle (days 1 and 2), Leucovorin: 200 mg/m2 (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
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
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WC2A 3PX
+44 (0)207 317 5186
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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No