ISRCTN55293778 https://doi.org/10.1186/ISRCTN55293778

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00006479

Protocol serial number
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

Study type(s)

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex

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
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (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, 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	results	01/11/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes