

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
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2013	Condition category Cancer	☐ Individual participant data

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

Primary study design

Interventional

Study design

Randomised controlled trial

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