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SIOPEL-3 Liver Tumour Studies: hepatoblastoma and hepatocellular carcinoma

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 09/06/2017	**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

Protocol serial number
LT1998/01

Study information

Scientific Title
SIOPEL-3 Liver Tumour Studies: hepatoblastoma and hepatocellular carcinoma

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)
Treatment

Health condition(s) or problem(s) studied
Hepatoblastoma and hepatocellular carcinoma

Interventions
Standard risk hepatoblastoma
Arm 1:
Initial Treatment - 1 course cisplatin. Continuation treatment - 5 courses cisplatin/doxorubicin.
Surgery after course 3 (if feasible).
Arm 2:
Initial treatment - 1 course cisplatin. Continuation treatment - 5 courses cisplatin.
Surgery after course 3 (if feasible).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cisplatin, doxorubicin

Primary outcome(s)
Complete resection

Key secondary outcome(s))
Toxicity measures, survival and event-free survival

Completion date
31/12/2005

Eligibility

Key inclusion criteria

1. Diagnosis is hepatoblastoma
2. Pretext is I, II or III
3. No extrahepatic Involvement
4. Age <16 at diagnosis
5. No prior treatment
6. No primary surgery required
7. Lung CT scan performed
8. Initial serum alpha-feta protein value obtained (greater than or 100 ng/ml)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
16 years

Sex
All

Key exclusion criteria
Pretext 4, extra hepatic disease, lung metastases, tumour rupture.

Date of first enrolment
01/06/1998

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Great Ormond Street Hospital
London
United Kingdom
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Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research UK (CRUK) (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes