

SIOPEL-3 Liver Tumour Studies: hepatoblastoma and hepatocellular carcinoma

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 09/06/2017	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

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

WC1N 3JN

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes