

SIOPEL-3 Liver Tumour Studies: hepatoblastoma and hepatocellular carcinoma

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/06/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.siopeel.org/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 measure

Complete resection

Secondary outcome measures

Toxicity measures, survival and event-free survival

Overall study start date

01/06/1998

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

Age group

Child

Upper age limit

16 Years

Sex

Both

Target number of participants

500+

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

England

United Kingdom

Study participating centre

Great Ormond Street Hospital

London

United Kingdom

WC1N 3JN

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Trust Headquarters

Gwendolen House

Gwendolen Road

Leicester

England

United Kingdom

LE5 4QF

Sponsor type

Hospital/treatment centre

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, 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