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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

Study website
http://www.siopel.org/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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