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Study to assess the age-dependency in the clearance of doxorubicin in children with leukaemia and solid tumours

Submission date 02/09/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/09/2011	**Overall study status** Completed	
Last Edited 29/03/2016	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-measuring-doxorubicin-blood-levels-in-children-young-people-having-treatment-for-solid-tumours-and-leukaemia-the-epoc-study

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01095926

Clinical Trials Information System (CTIS)
2009-011454-17

Protocol serial number
8609

Study information

Scientific Title
Phase II pharmacokinetic study to assess the age-dependency in the clearance of doxorubicin in paediatric patients with solid tumours and leukaemia

Study objectives
Doxorubicin is widely used in the treatment of children's cancer, but little is known about how rapidly the drug is metabolised and removed from the body, particularly in very young children. The study brings together investigators in the UK, in France, Germany and Italy to investigate whether the rate of metabolism and removal is related to age or to the toxicity caused by treatment with doxorubicin. Because children's cancer is relatively rare, in order to recruit sufficient patients it is necessary to run the study in multiple clinical centres across four different countries. This study is funded by the FP7-programme of the European Union, specifically to obtain information on drugs like doxorubicin, where the drug is widely-used, but there are gaps in our knowledge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Research Ethics Committee, 26/04/2010, ref: 10/H090/22

Study design
Non-randomised, interventional and observational

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Paediatric Oncology, Leukaemia (acute), Leukaemia (chronic), Multiple Sites, Leukaemia (acute myeloid), Leukaemia (acute lymphoblastic), Leukaemia (acute promyelocytic)

Interventions
1. Collection of blood sample for genetic analysis
2. Collection of blood samples for drug and toxicity marker analysis

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Doxorubicin

Primary outcome(s)
The primary outcome will be when the data has been collected & analysed from all the 100 patients at the end of the study.

1. Pharmacokinetic data to enable assessment of age-dependency of doxorubicin in paediatric patients
2. Pharmacokinetic data available on 100 paediatric patients including at least 5 patients <1 year old

Key secondary outcome(s))
The outcome of an interim analysis on the data from the first 30 patients is expected to be reported early 2012

Completion date
28/02/2012

Eligibility

Key inclusion criteria
1. Patients less than or equal to 17 years of age
2. Plan to receive at least 2 cycles of doxorubicin
3. Must be enrolled in a national or European protocol for treatment of Wilms 4.Turmours, Neuroblastoma, Soft tissue sarcome, Ewing Sarcoma or Acute lymphoblastic leukaemia and must be treated with doxorubicin according to that protocol or patients under 3 years enrolled or listed in any national or European study protocol for any paediatric malignancy.
5. Patients, parents or legal representative(s) must provide written informed consent to participate in the trial according to national regulations
6. Patients that are able to understand should provide assent to participate in the trial
7. Life expectancy is >3 months
8. Karnofsky performance status of >/=70%
9. Additional blood withdrawal is acceptable to the patient. (the decision is left to the investigator)
10. Either male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
17 years

Sex
All

Key exclusion criteria

Prior cardiac problems

Date of first enrolment
16/01/2011

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern Institute of Cancer Research
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Commission of the European Communities (Europe)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes