

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

<b>Submission date</b> 02/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/03/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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>

## Study website

<http://epocstudy.org/trial/epoc/default.aspx>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Alison Steel

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2009-011454-17

### IRAS number

**ClinicalTrials.gov number**

NCT01095926

**Secondary identifying numbers**

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

**Secondary study design**

Non randomised study

**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**

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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

16/01/2011

## **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. Tumours, Neuroblastoma, Soft tissue sarcoma, 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  $\geq 70\%$

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

**Age group**

Child

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 100; UK Sample Size: 25

**Key exclusion criteria**

Prior cardiac problems

**Date of first enrolment**

16/01/2011

**Date of final enrolment**

28/02/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**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)

### Sponsor details

Queen Victoria Road  
Newcastle Upon Tyne  
England  
United Kingdom  
NE1 4LP

### Sponsor type

Hospital/treatment centre

### Website

<http://www.newcastle-hospitals.org.uk/>

### ROR

<https://ror.org/05p40t847>

## Funder(s)

### Funder type

Government

### Funder Name

Commission of the European Communities (Europe)

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2015		Yes	No