

# Paediatric accelerator mass spectrometry evaluation research study

<b>Submission date</b> 22/10/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2017	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

There is an urgent need to ensure that medicines given to children are assessed sufficiently. A range of methods have been proposed to do this. The aim of the study is to apply and test a method called microtracer dosing with accelerator mass spectrometry (AMS) bioanalysis, using paracetamol as a model drug and find out its effects on newborn, infants and toddlers. The results are compared with the information available in previous research that used standard methods. This study could establish a way for AMS studies to be a part of Paediatric Investigation Plans for development of new drugs. This will mean that new drugs can be given to children earlier than in current practice.

### Who can participate?

Male and female hospitalised infants aged between preterm up to 2 years

### What does the study involve?

A single microdose of radioactive paracetamol will be given to infants whose age range is preterm up to 2 years of age orally or injected through the vein. A maximum of 20 extra drops of blood is taken from each participant. This is spread over the 12 hours after the isotope dose is received. The total amount of blood taken will be 1ml. The blood is taken via the lines already in place. The maximum length of participation in the study is up to 48 hours after giving the study drug.

### What are the possible benefits and risks of participating?

The participants will not gain any direct benefit. The benefits from this study are for other babies in the future as the information gathered in this study becomes available. The risks due to paracetamol will be minimal as this microdose is less than a millionth of the dose normally given to newborn babies and infants. There are no anticipated safety issues relating to exposure to the radioactive drug.

### Where is the study run from?

1. Liverpool Womens NHS Foundation Trust, UK (lead centre)
2. Tartu University Hospital, Childrens Clinic, Estonia
3. Alder Hey Childrens NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?  
The study started in November 2012 and will run for 2 years.

Who is funding the study?  
ERA-NET PrioMedChild (Priority Medicines for Children), Netherlands.

Who is the main contact?  
Miss Louise Hardman  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
1.0

## Study information

**Scientific Title**  
A multi-centre clinical study to evaluate the use of a microtrace dose of <sup>14</sup>C-labelled paracetamol and Accelerator Mass Spectrometry (AMS) bioanalysis as new tools in drug development to determine pharmacokinetics in neonates, infants and toddlers

**Acronym**  
PAMS

**Study objectives**  
14C-labelled microdose paracetamol has similar PK to standard, therapeutic paracetamol.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

## **Primary study design**

Observational

## **Study design**

Multicentre observational open-label study

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Medicines for Children; Paediatrics

## **Interventions**

No specific study-related assessments will be conducted.

No haematology, biochemistry or blood gas studies samples will be taken for the purposes of this study. The most recent blood samples will be included in the data if they are taken 24 hours before the drug is administered in neonates and up to 3-7 days before for older infants. A maximum of 5 blood samples after drug administration will also be collected. Details of blood results that will be collected for the study data are:

Biochemistry: Plasma creatinine, Na<sup>+</sup>, K<sup>+</sup> Cl, AST, ALT, alkaline phosphatase, total bilirubin, conjugated bilirubin, albumin, total calcium, corrected calcium, magnesium, C-reactive protein.  
Full Blood Count: Hgb, total white cell count, differential white cell count, MCV, MCH, MCHC and platelets.

Blood gas: pH, glucose, lactate, ionized calcium

In participants with urinary catheters in place the urine collection bag will be emptied immediately before the microdose is administered. Timed samples of urine will be collected for 48 hours after the microdose is administered.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

A noncompartmental model of paracetamol disposition

## **Key secondary outcome(s)**

A population model of the whole dataset taking account of all the variables

## **Completion date**

11/11/2014

## **Eligibility**

**Key inclusion criteria**

1. Infants and toddlers from preterm neonates (32-36 GW at birth) up to 2 years of age
2. Having intravenous or intra-arterial access suitable for blood sampling
3. Written informed consent prior to any study-specific procedures
4. Able to tolerate oral administration for oral administration group

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. History of allergy or hypersensitivity to paracetamol;
2. Serious hepatic and/or renal impairment defined as creatinine > 150 micromol or AST or ALT > 200
3. Be otherwise unsuitable for the study, in the opinion of the investigator
4. Extracorporeal membrane oxygenation (ECMO)
5. Haemofiltration, peritoneal dialysis, haemodialysis

**Date of first enrolment**

12/11/2012

**Date of final enrolment**

11/11/2014

**Locations****Countries of recruitment**

United Kingdom

England

Estonia

**Study participating centre**

**Liverpool Women's NHS Foundation Trust**

Liverpool

United Kingdom

L8 7SS

# Sponsor information

## Organisation

Liverpool Women's NHS Foundation Trust (UK)

## ROR

<https://ror.org/04q5r0746>

# Funder(s)

## Funder type

Research organisation

## Funder Name

ERA-NET PrioMedChild (Priority Medicines for Children) (Netherlands)

# 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?
<a href="#">Results article</a>	results	01/07/2015		Yes	No