

# Comparing intervention levels for the support of blood pressure in extremely premature newborn babies

<b>Submission date</b> 13/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/04/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Although many of the problems of extremely preterm babies may be related to disturbances of the circulatory system (body system that controls blood flow), there is a lack of agreement regarding interventions (treatment) for low blood pressure in these babies. The lower limit of blood pressure requiring support in premature babies is still uncertain.

### Who can participate?

This study will recruit newborn babies of 23-28 weeks gestation admitted to a single neonatal unit.

### What does the study involve?

A total of 60 extremely preterm babies, will be randomised to one of three different blood pressure intervention levels at which standard treatments for low blood pressure will be started:

1. Active: Support blood pressure if it falls below 30mmHg
2. Moderate: Support blood pressure if it falls below the baby's gestation in mmHg
3. Permissive: Do not intervene unless low blood pressure is accompanied by evidence of impaired blood flow

This is a initial study to determine whether different intervention levels achieve different blood pressures and rates of drug treatment. It will also compare short and long term complications as well as organ blood flow between the groups.

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

There will no immediate benefit to those taking part, but information from this study may help other premature babies and may be used to plan larger studies looking at clinical outcomes. These intervention levels are all in use in various different neonatal units. The study will not carry appreciable benefits or risks for participants, beyond those associated with extreme prematurity itself.

### Where is the study run from?

This is a single centre study to be conducted in Barts Health NHS Trust.

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

Who is funding the study?  
The study will commence as an internally funded study by Centre for Paediatrics, Blizard Institute, Barts and the London School of Medicine and Dentistry, but external funding has been applied for.

Who is the main contact?  
Dr Steve Kempley  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2012-v4

## Study information

**Scientific Title**  
A pilot randomised trial comparing intervention levels for the support of blood pressure in extremely premature newborn babies

**Study objectives**  
Different approaches to blood pressure intervention will result in different usage rates of inotropic agents and levels of achieved blood pressure, in extremely premature newborn infants

(less than or equal to 28 weeks gestation). These findings, together with the rates of complications found in the whole study, will be used to design a larger multicentre study.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised 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**

Extreme prematurity, neonatal care, circulatory support

**Interventions**

The study intervention will be allocate babies to a particular blood pressure level at which staff will commence standard treatments for low blood pressure. Patients will be allocated to one of the following three intervention levels:

1. Active: Support blood pressure if it falls below 30mmHg
2. Moderate: Support blood pressure if it falls below the babys gestation in mmHg
3. Permissive: Do not intervene unless low blood pressure is accompanied by evidence of impaired blood flow

In each arm of the trial, patients will receive the same treatments for low blood pressure, once they reach the intervention level.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Mean arterial blood pressure during the first week of life (collected hourly for the first 12 hours and 4-hourly thereafter)
2. Use of inotropes and duration of their use

### **Secondary outcome measures**

1. Death or parenchymal brain abnormality on cerebral ultrasound before discharge home
2. Death before discharge home from hospital
3. Periventricular leucomalacia (on cranial ultrasound at or before 36 weeks corrected gestational age)
4. Parenchymal periventricular haemorrhage (on cranial ultrasound on Day 1 and by one week)
5. Other periventricular haemorrhage
6. Acquired gastrointestinal pathology (necrotising enterocolitis, perforation or GI surgery)
7. Treatment for patent ductus arteriosus (drugs or ligation)
8. Maximum serum creatinine in the first 2 weeks of life
9. Maximum serum potassium level
10. Duration of respiratory support
11. Chronic lung disease (defined as oxygen dependency at 36 weeks post-conceptual age)
12. Use of postnatal steroids including hydrocortisone
13. Duration of neonatal care at each British Association of Perinatal Medicine (BAPM) care level (this is the basis for charging for care and a good marker of health service costs)
14. Neurodevelopmental status at routine developmental follow-up

### **Overall study start date**

01/09/2012

### **Completion date**

31/08/2014

## **Eligibility**

### **Key inclusion criteria**

Extremely preterm infants will be eligible to take part in the study if they are:

1. Born at less than or equal to 28 weeks gestation
2. Admitted to our neonatal unit
3. Recruited and randomised in the first 12 hours of life

### **Participant type(s)**

Patient

### **Age group**

Neonate

### **Sex**

Both

### **Target number of participants**

60

### **Total final enrolment**

**Key exclusion criteria**

Known major congenital malformation

**Date of first enrolment**

01/09/2012

**Date of final enrolment**

31/08/2014

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Centre for Paediatrics**

London

United Kingdom

E1 2AT

## **Sponsor information**

**Organisation**

Barts Health NHS Trust (UK)

**Sponsor details**

c/o Mr Gerry Leonard

Queen Mary Innovation Centre

Lower Ground Floor

5 Walden Street

London

England

United Kingdom

E1 2EF

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.bartsandthelondon.nhs.uk/our-services/research-and-development/>

ROR

<https://ror.org/00b31g692>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Centre for Paediatrics, Blizard Institute, Barts and the London School of Medicine and Dentistry (UK)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to a lack of approval from the research ethics committee to do so.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2018	26/11/2019	Yes	No
<a href="#">Results article</a>		01/11/2018	26/11/2019	Yes	No
<a href="#">Results article</a>		01/05/2019	19/04/2021	Yes	No