ISRCTN83507686 https://doi.org/10.1186/ISRCTN83507686

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

Submission date
13/07/2012

Recruitment status
No longer recruiting

Registration date
01/10/2012

Overall study status
Completed

Last Edited
26/04/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 babys 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
s.t.kempley@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Kempley

Contact details
Centre for Paediatrics
Blizard Institute
4, Newark Street
London
United Kingdom
E1 2AT
+44 (0)20 7882 2615
s.t.kempley@qmul.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
60

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
United Kingdom

England

Study participating centre

Centre for Paediatrics
London
United Kingdom
E1 2AT

Sponsor information

Organisation
Barts Health NHS Trust (UK)

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

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?
Results article	results	01/11/2018	26/11/2019	Yes	No
Results article		01/11/2018	26/11/2019	Yes	No
Results article		01/05/2019	19/04/2021	Yes	No