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Non-invasive blood pressure measurement in neonates: comparative analysis of different methods for reliability

Submission date 23/08/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/09/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/09/2015	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

We are currently undertaking a study to compare the various methods to measure blood pressure in preterm babies. In babies, it is important to keep blood pressure in the normal range as low or high blood pressure can have negative impact on various vital organs, so the accurate measurement of blood pressure is essential. The most reliable method to measure blood pressure is via putting a catheter/arterial line in one of the arteries of the baby and then directly measuring the blood pressure. This is most commonly done by putting the catheter in one of the blood vessels in the umbilical cord. However, this can be a technically challenging procedure and may not be successful at times. Also there can be some complications associated with this if the catheter is left in for a long time. This means that we need a simpler and more reliable method to measure blood pressure. One of the most commonly used methods is an automated system where the cuff is applied to the babies' arm and a reading comes up on the monitor. The other less commonly used method is a Doppler method. This is a hand held instrument which picks up sounds as the blood flows in the arteries. This is a similar method to cuff blood pressure and does not involve any invasive procedures. It has been found to be closest to the arterial (direct) blood pressure in several studies in older children and adults. The aim of this study is to compare the blood pressures obtained by these methods and find out which method correlates best with arterial blood pressure in very premature babies.

Who can participate?

In this study, we will recruit babies who are less than 28 weeks gestation. These are the babies who are most likely going to need an arterial line inserted as part of their routine intensive care.

What does the study involve?

The study does not involve any extra investigation or blood testing. In addition to the blood pressure measurement by the arterial line, the participating babies will also have their blood pressured measured by two non-invasive methods (Doppler and cuff blood pressure).

What are the possible benefits and risks of participating?
There are no perceived benefits or disadvantages of taking part in this study and all the babies will receive best standard care as any other baby who is not in the study.

Where is the study run from?
Neonatal intensive care unit in James Cook University Hospital in Middlesbrough (UK).

When is the study starting and how long is it expected to run for?
October 2014 to October 2015.

Who is funding the study?
South Tees Hospitals NHS Foundation Trust (UK).

Who is the main contact?
Dr Shalabh Garg

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
133892

ClinicalTrials.gov number

Secondary identifying numbers
2014001; IRAS project ID:133892

Study information

Scientific Title
Non-invasive blood pressure measurement in neonates: comparative analysis of different methods for reliability: an observational study

Acronym
NiDOP (Non invasive Doppler and Oscillometric Pressures)

Study objectives
The measurement of blood pressure by non-invasive oscillometric method is a common practice in the neonatal units. Several studies have shown that this type of non-invasive blood pressure measurement sometimes over-estimates the blood pressure leading to false reassurance of nursing and medical staff. The accuracy of this method is even more unreliable during the hypotensive periods in this group of patients. The invasive blood pressure monitoring by indwelling arterial catheter (Umbilical arterial catheter or peripheral arterial catheter) is considered to be the gold standard but is not always possible.
The other non-invasive method of blood pressure monitoring is by Doppler ultrasound measurement. This has been shown to be better correlated to arterial blood pressure in various studies. Although the manufacturers claim that with the advancement of technology, the newer generation of oscillometric monitors are better correlated with arterial blood pressure but the recent studies in paediatric and adult intensive care units do not prove this. In spite of the reservations about the reliability of the oscillometric method, it is still used widely in majority of neonatal units and critical decisions are made based on these measurements. The direct blood pressure measurement by placement of arterial catheter is a difficult procedure and is not without complications. Also, once the arterial catheter is removed (usually within a week), accurate measurement of blood pressure measurement is important for management.
We did a pilot survey and found that there are significant variations in practices in terms of measuring blood pressure and treating. There is no proven right or wrong way of measuring blood pressure because of lack of evidence. We hope that this study will provide impetus to adopt a particular method of measuring blood across UK. We conducted this survey to study the variations in practices amongst Level 3 units across England (45 units). We came up with following results:
1. 89% units used both indwelling arterial lines and oscilliometric methods and only 5 units used Doppler in addition.
2. 65% units have written guidelines on the treatment of hypotension.
3. 82% units used dopamine as the first inotropic agent.
4. 40 (90%) units routinely used fluid bolus as first step of treatment of hypotension. Two units used fresh frozen plasma if the perfusion was low after first bolus.
5. 20 units (45%) kept the umbilical arterial lines for as long as needed but the rest of units kept

them for different periods (3-14 days).
6. There are 9 different makes of oscillometric monitors that are in use in England and that too with different versions.

The current literature suggests (paediatric, adults and animals) that Doppler blood pressure is better correlated with the arterial blood pressure. In extreme preterm babies, that data is not available. We conducted a pilot survey of all the tertiary neonatal units in England and found that most units still use cuff blood pressure measurements (oscillometric method) in neonates. Through this observational study, our aim is to study which non-invasive method of blood pressure measurements (Doppler versus Oscillometric Methods) in extreme preterm neonates correlates better with arterial (invasive) blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 2, REC ref:14/NE/1031

Study design
Observational study

Primary study design
Observational

Secondary study design
Other

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
Blood pressure management in neonates

Interventions
Where possible, parents will be approached prior to delivery and given information regarding the trial. If this is not possible then they will be approached soon after clinical decision has been made to put in an umbilical arterial catheter. Clinical team involved with care of the baby will give patient information leaflets to the parents/guardians and offer explanation. Parents /guardians will be given time to read the leaflet and then approached again within 48 hours of arterial catheter placement for consent. Informed written consent for the trial will be obtained from either of the parents/guardians with parental responsibility by members of research team. If consent is given, and providing no contra-indications occur, the baby will be included in the study.
Blood pressure will be measured in the recruited babies by oscillometric/cuff and Doppler

methods and will be compared with corresponding blood pressure measurements by arterial catheter. Each baby who has indwelling arterial catheter (umbilical arterial catheter) will have blood pressure measured 4-6 hourly by oscillometric and Doppler methods till the time arterial catheter remains in situ. The blood pressure measured by Doppler method will be recorded under two categories- one obtained at the appearance of sound from Doppler probe and other at the time of appearance of the trace on the pulse oximeter.
Measurements of blood pressure indirectly by cuff and Doppler methods will be done when baby will have cares done routinely by nursing staff. Cares happen every 4 to 6 hours depending upon how sick the baby is. A total of 10 measurements will be taken by cuff and Doppler methods over 24-48 hours coinciding with routine times of cares. After 10 measurements, recruitment of that particular patient will be complete. There will be no effect on routine care of the baby. There are no anticipated side effects.

Intervention Type

Phase
Not Applicable

Primary outcome measure
Correlation of blood pressure measurement by oscillometric/cuff method and Doppler method with direct method of blood pressure measurement from an umbilical artery catheter.

Secondary outcome measures
1. Duration of arterial catheter placement (in days)
2. Inotropic support (Choice and duration)
3. Amount and number of fluid boluses given for hypotension
4. Difference in Doppler blood pressure obtained firstly by appearance of sound and secondly by trace on saturation monitor
5. Complications related to arterial catheters

These will be recorded in case report file.

Overall study start date
01/10/2014

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Any baby born between and including 23+0 and 28+0 weeks of gestation
2. Admitted to neonatal unit
3. Needing arterial catheter placement for clinical reasons

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Babies with no arterial catheter in situ
2. Babies with any congenital heart disease or cardiac arrhythmias documented on ECG
3. Babies with congenital limb defects

Date of first enrolment
01/01/2015

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Middlesbrough
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Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
James Cook University Hospital (UK)

Results and Publications

Publication and dissemination plan
We intend to present the results in an international meeting as well as publish result in medical journal. The dates are not confirmed as yet.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No