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Comparison of two different monitors (electrocardiogram and pulse oximeter versus pulse oximeter alone) for monitoring heart rate in newly born infants: A randomised study

Submission date
15/03/2017

Recruitment status
No longer recruiting

Registration date
04/05/2017

Overall study status
Completed

Last Edited
11/12/2018

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
Immediately after birth, a baby's heart rate (HR) is measured to determine if babies need help with their breathing. This was traditionally done using a stethoscope. Over the last ten years, pulse oximeters have increasingly been used to measure HR after birth. Pulse oximeters (PO) are machines which non-invasively measure blood oxygen levels and HR. PO measures HR by counting the number of pulses in the hand. They have been used to monitor infants HR for many years. More recently, electrocardiograms (ECG) have been recommended to measure HR in newly born infants. This method uses sensors to measure HR. For either method, it is important that information is displayed quickly, especially right after birth when it is critical to know if a baby requires help breathing. The National Maternity Hospital (Ireland) current uses PO to measure and monitor HR of a baby right after birth. However, the hospital has machines that combine both ECG and PO that are being used in the neonatal unit (post birth unit). These could be used instead of PO to measure HR right after birth if they are able to quickly measure and monitor HR of babies. The aim of this study is to compare two different heart monitoring machines to see how quickly they are able to provide HR information.

Who can participate?
Babies born at the National Maternity Hospital (Ireland)

What does the study involve?
Newborn babies are randomly allocated to one of two groups. Those in the first group have their HR measured using a monitor that combines both an ECG and a PO. This involves an ECG sensor and a PO monitored placed around their right wrist or hand. Those in the second group have their HR measured only using a PO monitor that is placed around their right wrist or hand. The time taken for each monitor to display the babies HR is recorded and there is no further follow up involved for participants.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
National Maternity Hospital (Ireland)

When is the study starting and how long is it expected to run for?
February 2017 to June 2017

Who is funding the study?
National Maternity Hospital (Ireland)

Who is the main contact?
Professor Colm O'Donnell

Contact information

Type(s)
Scientific

Contact name
Prof Colm O'Donnell

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Additional identifiers

Protocol serial number
SHEEP001

Study information

Scientific Title
A randomised study of heart rate estimation comparing two monitors (electrocardiogram plus pulse oximeter versus pulse oximeter alone) in newly-born infants

Acronym
SHEEP

Study objectives

Electrocardiogram and pulse oximetry gives a heart rate (HR) more quickly than pulse oximetry alone in the first minutes of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethic Committee at the National Maternity Hospital, 06/03/2017, ref: EC04.2017

Primary study design
Observational

Study design
Single-centre unmasked randomised parallel group study

Study type(s)
Other

Health condition(s) or problem(s) studied
Delivery room care of newborn infants

Interventions
Newly-born infants are transferred to an open resuscitation cot as practicable after birth. Infants are randomly allocated to one of two groups.

Intervention group: Infants are monitored using the Intellivue X2 monitor (Philips, Eindhoven, Netherlands) which incorporates electrocardiogram (ECG) and pulse oximetry (PO). The infants have the ECG applied before the PO sensor is placed around their right wrist or hand and attached to the machine.

Control group: Infants are monitored with a Nellcor PM1ON portable PO (Covidien, Boulder CO, USA). The PO sensor is placed around the right wrist or hand and then attached to the machine. Infants are observed to ensure that they are well as is standard with any birth.

The time taken for each monitor to display the infants heart rate (HR) is recorded and the infants participation in the study ends at this point and there is no further follow-up. The duration of participation is around five minutes.

Intervention Type
Other

Primary outcome(s)
Time to first heart rate from monitor application measured in seconds using a stopwatch.

Key secondary outcome(s)
1. Failure of monitoring (i.e. heart is not displayed) is measured within 5 minutes of applying the monitor
2. Time taken to apply monitor is measured in seconds using a stopwatch
3. Skin damage with leads/sensors are measured by visual inspection at around five minutes

Completion date
30/06/2017

Eligibility

Key inclusion criteria
All infants (term and pre-term) born at National Maternity Hospital.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Major congenital anomalies
2. No antenatal consent

Date of first enrolment
17/04/2017

Date of final enrolment
15/06/2017

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Neonatal Unit
Holles Street
Dublin
Ireland
D02 YH21

Sponsor information

Organisation
National Maternity Hospital

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Maternity Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Previous publication and dissemination plan:
Submission of results for presentation at the annual meeting of the European Society for Paediatric Research and Pediatric Academic Societies.

IPD sharing plan:
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019		Yes	No
Basic results		15/10/2018	15/10/2018	No	No