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Comparing different monitors for high-risk babies in the delivery room

Submission date
17/07/2018

Recruitment status
No longer recruiting

Registration date
19/07/2018

Overall study status
Completed

Last Edited
18/01/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
All newborn babies are assessed soon after birth. The heart rate is measured to see if they need help with their breathing. This may be done done by listening to the heart with a stethoscope. However, newborn babies often have their heart rate measured in other ways.
Electrocardiogram (ECG) is routinely used to measure a baby's heart rate in the neonatal unit, by counting electrical impulses using stickers placed on the chest. Pulse oximeters may also be used to measure heart rate. While these machines are usually used to measure blood oxygen levels in the neonatal unit using a sensor that is placed around the hand, they also measure the heart rate by counting pulsations.
When the heart rate is measured immediately after birth, it is important that information is available quickly. For years we have measured the heart rate by listening with a stethoscope or using a pulse oximeter. More recently, ECG has been recommended to measure heart rate immediately after birth. However, we use machines that combine both ECG and pulse oximetry in the neonatal unit. This study aims to compare two different heart monitoring machines, one combining ECG and pulse oximetry, and the other using only pulse oximetry, to see how quickly they provide heart rate information after birth.

Who can participate?
Newly-born babies of both genders who are born between 29 and 35 weeks of gestation

What does the study involve?
Babies will be randomly assigned to one of two groups - the intervention or the control group. In the intervention group, babies will have their heart rate measured using a monitor that combines both ECG and a pulse oximeter. Those in the control group have their heart rate measured only using a pulse oximeter. The time taken for each monitor to display the heart rate is recorded and there is no further follow up involved for participants.

What are the possible benefits and risks of participating?
The possible benefit of taking part is that babies in this study may have their heart rate determined more quickly after birth. There are no known risks to participants taking part in this study.

Where is the study run from?
National Maternity Hospital, Dublin, Ireland

When is the study starting and how long is it expected to run for?
December 2017 to October 2019

Who is funding the study?
National Children's Research Centre, Dublin (Northern Ireland)

Who is the main contact?
Prof. Colm O'Donnell
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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
SHEEP2

Study information

Scientific Title
Study comparing Heart rate Estimation using Electrocardiogram in addition to pulse oximetry versus Pulse oximetry alone in high-risk infants at birth: SHEEP2

Acronym
SHEEP2

Study objectives

Electrocardiogram (ECG) 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)
National Maternity Hospital, Dublin, Ireland, 13/03/2018, EC 05.2018

Study design
Interventional single-centre, unmasked, randomised parallel group study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

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

Interventions
Infants will be randomly assigned in a 1:1 ratio into the intervention or the control group. The groups assignment schedule will be stratified by gestational age (29 – 31^6, 32 – 34^6) and generated in blocks of 4 using a random number table. The schedule will be kept concealed from investigators and clinicians attending the deliveries to care for the infants. Groups assignment will be written on cards that are contained in sequentially numbered sealed opaque envelopes. An envelope from the appropriate stratum will be opened shortly before delivery.
Infants in the intervention group will be monitored with the IntelliVue X2 (Philips, Eindhoven, Netherlands), a machine that combines ECG and pulse oximeter.
Infants in the control group will be monitored with a pulse oximeter (Nellcor, Covidien, Boulder CO, USA) alone
Infants will be monitored using the randomly assigned monitor in the delivery room. The majority of data will be collected in the delivery room, the last data point (temperature) will be acquired on admission to the neonatal unit. This time point will be variable for enrolled infants, but will be within 30 minutes of birth in the majority.

Intervention Type
Other

Primary outcome measure

Time (seconds) to first heart rate from monitor application, measured with a stopwatch from a video recording within 30 minutes of birth

Secondary outcome measures
1. Time (seconds) from birth to first heart rate display by monitor, measured with a stopwatch from video recording
2. Time (seconds) taken to apply monitor, measured with a stop watch from video recording
3. Failure of monitor to display heart rate within 5 minutes of birth, determined from video recording
4. Reapplication of monitor, determined from video recording
5. Initial bradycardia (heart rate < 100 beats per minute) on pulse oximetry, determined from video recording
6. Intermittent pulse oximetry readings, determined from video recording
7. Number of handling events, determined from video recording
8. Duration (seconds) of handling events, measured with a stopwatch from video recording
9. Use of mask respiratory support, determined from video recording
10. Time (seconds) to mask respiratory support, measured with a stopwatch from video recording
11. Use of chest compressions, determined from video recording
12. Time (seconds) to chest compressions, measured with a stopwatch from video recording
13. Endotracheal intubation, determined from video recording
14. Time (seconds) to endotracheal intubation, measured with a stopwatch from video recording
15. Infants temperature (°C), measured with a digital thermometer on admission to neonatal unit

Overall study start date
01/12/2017

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Infant
2. Born between 29 and 35 weeks of gestation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
100

Total final enrolment
39

Key exclusion criteria
Major congenital anomalies

Date of first enrolment
01/08/2018

Date of final enrolment
30/07/2019

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Holles Street, Dublin 2
Dublin
Ireland
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Sponsor information

Organisation
National Maternity Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type

Not defined

Funder Name
National children's Research Centre provide salary support for Madeleine Murphy

Results and Publications

Publication and dissemination plan
We will present the findings of our study at local and international scientific conferences, and submit them for publication in a peer-reviewed scientific journal

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as ethical approval to do so has not been sought.

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	15/01/2021	18/01/2021	Yes	No