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Placing preterm infants on their back or in recovery position on their left side at birth

Submission date
19/09/2012

Recruitment status
No longer recruiting

Registration date
16/10/2012

Overall study status
Completed

Last Edited
08/02/2016

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Premature babies are routinely placed flat on their backs after birth. Though the majority of them breathe spontaneously, they often have difficulty breathing and are given support in the delivery room. Obstruction of the airway of premature babies during breathing support in the delivery room is common. Spontaneously breathing premature infants are often placed on their side or on their front in the nursery as they appear to breathe better in these positions than if they are placed on their back. Older children and adults with reduced consciousness who breathe spontaneously are placed on their side in the recovery position to keep their airway open. We aim to determine whether premature babies breathe more effectively, demonstrated by having higher oxygen saturation (SpO2), at 5 minutes of life if they are placed on their side rather than on their back.

Who can participate?
Babies born at < 32 weeks gestation who do not have major congenital anomalies will be enrolled.

What does the study involve?
They will be randomly assigned to be placed on their back or on their left side just before birth and placed in their assigned position when they arrive on the resuscitation table; their care will be identical in all other respects. They will have a pulse oximeter that will measure their SpO2 placed on their right wrist shortly after birth. The SpO2 at 5 minutes of life of all babies in both groups will recorded and compared.

What are the possible benefits and risks of participating?
It is possible that babies in one group may breathe more effectively than the other, though this will not be known until all babies have been enrolled and the data has been analysed. We know of no additional risks above those associated with prematurity that babies will encounter by participating in this study.

Where is the study run from?
The National Maternity Hospital, Holles Street, Dublin, Ireland.

When is study starting and how long is it expected to run for?
It will start in October 2012 and should be completed in 9 months.

Who is funding the study?
The study is supported by The National Childrens Research Centre, Dublin, Ireland.

Who is the main contact?
Dr Colm ODonnell
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Contact information

Type(s)
Scientific

Contact name
Dr Colm O'Donnell

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BREL001

Study information

Scientific Title
A randomised trial of placing preterm infants on their back or in recovery position on their left side at birth

Acronym
BREL

Study objectives

Preterm infants breathe more effectively after birth if they are placed on their left side than if they are placed on their backs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Maternity Hospital Research Ethics Committee, Dublin, Ireland, 17/09/2012

Study design
Randomised controlled 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
Prematurity, respiratory distress syndrome

Interventions
Placement in the recovery position on the left side or on their back

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Oxygen saturation (SpO2) measured pre-ductally (i.e. from the right upper limb) at 5 minutes of life

Secondary outcome measures
1. Heart rate (HR) at 5 minutes
2. SpO2 at 10 minutes
3. HR at 10 minutes
4. Apgar score at 1 minute

5. Apgar score at 5 minutes
6. Apgar score at 10 minutes
7. Time to SpO2 > 90%
8. HR < 100 in the DR
9. Duration of HR < 100 in the DR
10. Use of CPAP in the DR
11. Use of PPV in the DR
12. Use of > 30% oxygen in the DR
13. Maximum FiO2 in the DR
14. Intubation in the DR
15. Chest compressions in the DR
16. Volume resuscitation in the DR
17. Intubation during hospitalisation
18.Surfactant use
19. Duration of ventilation (hours)
20. Duration of CPAP (days)
21. Postnatal corticosteroid use
22. Bronchopulmonary dysplasia ¨C oxygen therapy at 28 days of life
23. Chronic lung disease oxygen therapy at 36 week's postmenstrual age
24. Cranial ultrasound abnormalities (intraventricular haemorrhage, cystic PVL, ventricular dilatation)
25. Medical treatment for PDA
26. PDA ligation
27. NEC Bells stage 2
28. Retinopathy of prematurity
29. Duration of hospital stay
30. Death before discharge from hospital

Overall study start date
19/10/2012

Completion date
30/06/2013

Eligibility

Key inclusion criteria
Infants born at the NMH at < 32 weeks gestation (i.e. up to 31+6 weeks)

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
82

Key exclusion criteria
Infants with a major congenital anomaly, for example:
1. Diaphragmatic hernia
2. Cardiac anomaly other than patent ductus arteriosus
3. Ventricular septal defect or atrial septal defect
4. Gastroschisis
5. Omphalocoele
6. Oesophageal atresia with tracheo-oesophageal fistula Pierre-Robin sequence

Date of first enrolment
19/10/2012

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Ireland

Study participating centre
The National Maternity Hospital
Dublin
Ireland
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Sponsor information

Organisation
The National Maternity Hospital (Ireland)

Sponsor details
c/o Dr Colm O'Donnell
Neonatal Intensive Care Unit
Dublin
Ireland
2

Sponsor type
Hospital/treatment centre

Website
http://www.nmh.ie/

ROR

https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Childrens Research Centre (Ireland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016		Yes	No