

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/02/2016	Condition category Neonatal Diseases	<input type="checkbox"/> 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 be 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 O'Donnell
codonnell@nmh.ie

Contact information

Type(s)
Scientific

Contact name
Dr Colm O'Donnell

Contact details
Neonatal Intensive Care Unit
The National Maternity Hospital
Holles Street
Dublin
Ireland
2
+353 (0)16 373 100
codonnell@nmh.ie

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. Omphalocele
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

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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