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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
19/09/2012		☐ Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
16/10/2012		[X] Results	
Last Edited 08/02/2016	Condition category Neonatal Diseases	[] 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 codonnell@nmh.ie

Contact information

Type(s)

Scientific

Contact name

Dr Colm O'Donnell

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

ROR

https://ror.org/03jcxa214

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

National Childrens Research Centre (Ireland)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes