Respiratory support for preterm infants in the delivery room: Single nasal prong or face mask?

Submission date	Recruitment status	Prospectively registered
19/07/2010	No longer recruiting	☐ Protocol
Registration date 25/10/2010	Overall study status Completed	Statistical analysis plan
		[X] Results
Last Edited	Condition category	[] Individual participant data
25/10/2013	Neonatal Diseases	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NMH002

Study information

Scientific Title

Respiratory support for preterm infants in the delivery room: Single nasal prong or face mask? A randomised controlled trial

Acronym

DROPOM

Study objectives

Compared to preterm infants given respiratory support via a face mask, fewer premature infants given respiratory support via a single nasal prong are intubated and mechanically ventilated in the delivery room (DR)

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of The National Maternity Hospital, Dublin, approved on the 22nd February 2010

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory support of preterm infants at birth

Interventions

Respiratory support with a T-piece device using a single nasal prong (AKA short nasal tube AKA nasopharyngeal tube) compared to respiratory support with a T-piece device using a face mask.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Intubation and mechanical ventilation in the delivery room

Key secondary outcome(s))

- 1. Heart rate at five minutes
- 2. Use of supplemental oxygen in the DR
- 3. Chest compressions in the DR
- 4. Use of adrenaline and volume resuscitation in the delivery room
- 5. Apgar scores at 5 and 10 minutes
- 6. Temperature on arrival to NICU
- 7. Air leak (pneumothorax, pneumopericardium)
- 8. Intubation and mechanical ventilation ≤72 hours of life
- 9. Intubation and mechanical ventilation during hospital stay

- 10. Surfactant use
- 11. Duration of mechanical ventilation (hours & days)
- 12. Duration of CPAP (hours & days)
- 13. Duration of oxygen therapy (hours & days)
- 14. Oxygen therapy at 28 days
- 15. Oxygen therapy at 36 weeks post-menstrual age
- 16. Pulmonary haemorrhage
- 17. Pulmonary Interstitial Emphysema
- 18. Medical treatment for patent ductus arteriosus (PDA)
- 19. Surgical treatment for PDA
- 20. Treatment with postnatal corticosteroids
- 21. Intraventricular haemorrhage
- 22. Periventricular leukomalacia
- 23. Sepsis
- 24. Necrotising Enterocolitis
- 25. Retinopathy of prematurity
- 26. Hospital days
- 27. Death before hospital discharge

Completion date

30/06/2012

Eligibility

Key inclusion criteria

Infants born at The National Maternity Hospital at < 31 weeks gestation who receive respiratory support at birth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Αll

Key exclusion criteria

Infants with congenital anomalies

Date of first enrolment

19/07/2010

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

Ireland

Study participating centre Consultant neonatologist

Dublin Ireland 12

Sponsor information

Organisation

The National Children's Research Centre (Ireland)

ROR

https://ror.org/025qedy81

Funder(s)

Funder type

Research organisation

Funder Name

The National Children's 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?
Output type	Decails	Date created Date added 1 cer reviewed. I differ racing.

Results article results 01/08/2013 Yes No

Participant information sheet 11/11/2025 No Yes