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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	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
Intubation and mechanical ventilation in the delivery room

Secondary outcome measures
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

Overall study start date
19/07/2010

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

Age group

Neonate

Sex
Both

Target number of participants
142

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)

Sponsor details
Our Lady's Children's Hospital
Crumlin
Dublin
Ireland
12

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025qedy81

Funder(s)

Funder type
Research organisation

Funder Name
The National Children's 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	01/08/2013		Yes	No