

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

Submission date 19/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/10/2013	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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