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Prongs or mask for nasal continuous positive airway pressure (CPAP) in preterm infants

Submission date	Recruitment status	[_] Prospectively registered
21/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2012	Respiratory	

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
IRL/09/01

Study information

Scientific Title
Nasal prongs versus nasal mask for continuous positive airways pressure (CPAP) in preterm infants: a randomised controlled trial

Acronym
The POM trial

Study objectives
Giving nasal continuous positive airway pressure (CPAP) to preterm infants with prongs is more effective than with a nasal mask.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Ethics Committee of the National Maternity Hospital, Holles Street, Dublin, Ireland approved on the 14th July 2009

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
Respiratory distress of newborn

Interventions
Infants starting nasal continuous positive airway pressure (CPAP) using either the Infant Flow Driver or Infant flow SiPAP machine (both made by Viasys Healthcare, Yorba Linda CA, USA) in the neonatal intensive care unit (NICU) will be randomised to receive CPAP with either short binasal prongs or nasal mask of appropriate size. Infants will receive CPAP with the randomly assigned interface for the duration of CPAP treatment, which will be determined by the care givers. Infants will be followed up until death or hospital discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Intubation and mechanical ventilation less than or equal to 72 hours of starting treatment, indicated by at least two of the five criteria:
1. Worsening clinical respiratory distress
2. Recurrent apnoeic episodes
3. Oxygen requirement greater than 40% to keep oxygen saturations greater than 85% for greater than 30 minutes
4. pH less than 7.2 on two blood gases at least 30 minutes apart
5. Carbon dioxide (PCO2) greater than 9kPa on two blood gases at least 30 minutes apart

Secondary outcome measures
1. Use of nasal intermittent positive pressure ventilation (NIPPV), measured at death or hospital discharge
2. Duration of NIPPV (days), measured at death or hospital discharge
3. Number of intubations, measured at death or hospital discharge
4. Doses of surfactant given, measured at death or hospital discharge
5. Duration of mechanical ventilation (in days and hours), measured at death or hospital discharge
6. Duration of CPAP (in days and hours), measured at death or hospital discharge
7. Duration of oxygen therapy (days), measured at death or hospital discharge
8. Oxygen therapy at 28 days
9. Oxygen therapy at 36 weeks' post-menstrual age
10. Highest persistent oxygen requirement on CPAP, measured at death or hospital discharge
11. Home oxygen therapy, measured at hospital discharge
12. Air leaks, measured at death or hospital discharge
13. Use of diuretics, measured at death or hospital discharge
14. Duration of diuretic therapy, measured at death or hospital discharge
15. Sepsis (blood, urine or cerebrospinal fluid culture positivity), measured at death or hospital discharge
16. Medical treatment for patent ductus arteriosus, measured at death or hospital discharge
17. Ligation of patent ductus arteriosus, measured at death or hospital discharge
18. Time to 120 ml/kg/day enteral feeds, measured at death or hospital discharge
19. Gastrointestinal perforation, measured at death or hospital discharge
20. Necrotising enterocolitis, measured at death or hospital discharge
21. Intraventricular haemorrhage, measured at death or hospital discharge
22. Periventricular leukomalacia, measured at death or hospital discharge
23. Retinopathy of prematurity, measured at death or hospital discharge
24. Duration of hospital stay (days), measured at death or hospital discharge
25. Death before discharge and at latest follow-up

Overall study start date
22/07/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Infants born less than or equal to 30 weeks' gestation by best obstetric estimate, either sex
2. Receive nasal CPAP using the Infant Flow Driver or SiPAP machine (Viasys, Yorba Linda CA, USA) in the neonatal intensive care unit

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
120

Key exclusion criteria
Infants with congenital anomalies

Date of first enrolment
22/07/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Neonatology
Dublin
Ireland
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Sponsor information

Organisation
The National Children's Research Centre (Ireland)

Sponsor details
Our Lady's Children's Hospital
Crumlin
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Sponsor type
Research organisation

Website
http://www.childrensresearchcentre.org/index.html

ROR
https://ror.org/025qedy81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Our Lady's Children's Hospital (Ireland) - The Childrens Research Centre

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	01/11/2012		Yes	No