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The use of Low Flow Nasal Prongs Therapy in weaning nasal Continuous Positive Airway Pressure (nCPAP) in neonates. Anecdotal or Evidence Based?

Submission date
02/02/2010

Recruitment status
No longer recruiting

Registration date
24/02/2010

Overall study status
Completed

Last Edited
04/09/2013

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jan Miletin

Contact details
Neonatal Unit,
Coombe Women and Infants University Hospital,
Cork Street,
Dolphin's Barn,
Dublin
Ireland
D8
+353 (0)1 4085654
jmiletin@coombe.ie

Additional identifiers

Study information

Scientific Title

The use of Low Flow Nasal Prongs Therapy in weaning nasal Continuous Positive Airway Pressure (nCPAP) in neonates. A Multicentre Randomised Controlled Trial

Acronym
NOFLO Trial

Study objectives
The aim of the study is to determine if improved weaning of neonates less than 1500g from nCPAP can be observed using low flow nasal prongs therapy versus self ventilation after minimal nCPAP settings have been reached. We hypothesise that low flow nasal prong therapy will decrease failure rate of weaning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee, Coombe Women and Infants University Hospital, Dublin, Ireland approved on the 23rd of September 2009 (ref: 18 - 2009)
2. Ethics Commitee of Institute for Clinical and Experimental Medicine and Faculty of Thomayer Hospital, Prague, Czech Reupublic approved on the 13th of January 2010 (ref: 2500 - 09 [A 10-01-03])

Primary study design
Interventional

Study design
Multicentre randomised controlled parallel group trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Respiratory Distress Syndrome in very low birth weight infants.

Interventions
Intervention Group: Use of Low Flow Nasal Prongs therapy for weaning from nCPAP.
Control Group: Self Ventilation on weaning from nCPAP.

Study duration and monitoring will be for 5 consecutive days following weaning from nCPAP

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Failure rate of weaning from nCPAP. Failure of weaning defined by:
1. More than one self correcting apnoeic episode per hour (defined as a bradycardia < 100/min with concurrent saturations of less than 80% lasting ≥ 20 seconds) or one apnoeic episode requiring either stimulation or bag and mask ventilation.

2. Need for Oxygen to maintain saturations >85%.
3. A score of 6-10 on the Silverman-Anderson Respiratory Scale. This is an evaluation of respiratory status and work of breathing. A score of 6-10 will indicate moderate to severe respiratory distress.
If these criteria are reached they will be placed back on nCPAP at the settings they had been maintained on at the time of weaning.

Key secondary outcome(s)
1. Length of time to failure
2. Changes in status, assessed hourly
2.1. heart rate
2.2. respiratory rate
2.3. saturations
2.4. frequency of apnoeas
3. Change in Silverman - Anderson Respiratory Score, assessed every 4 hours

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Neonates with a birth weight of 1500g or less.
2. Ventilation support for a minimum of 48 hours (including nCPAP), with successful weaning to an oxygen concentration of room air.
3. Maintenance on a minimum end expiratory pressures of 3-5 cm of H2O on nCPAP. The neonate must be comfortably maintained on these nCPAP settings without significant apnoea or respiratory distress for at least 24 hours.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Neonates with associated congenital/respiratory/cardiac abnormality at the time of weaning of CPAP.

Date of first enrolment
01/02/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Czech Republic

Ireland

Study participating centre
Neonatal Unit,
Dublin
Ireland
D8

Sponsor information

Organisation
Coombe Women and Infants University Hospital (Ireland)

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Coombe Women and Infants University Hospital (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				

Results article	01/07/2013	Yes	No