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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/02/2010	**Overall study status** Completed	
Last Edited 04/09/2013	**Condition category** 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
N/A

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])

Study design
Multicentre randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please contact the investigating unit to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/02/2010

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

Age group
Neonate

Sex
Both

Target number of participants
78

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)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Coombe Women and Infants University Hospital (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	01/07/2013		Yes	No