

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	<input type="checkbox"/> Prospectively registered
Registration date 24/02/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/09/2013	Condition category Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

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 Committee of Institute for Clinical and Experimental Medicine and Faculty of Thomayer Hospital, Prague, Czech Republic 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)

Sponsor details

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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