

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

<b>Submission date</b> 02/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/09/2013	<b>Condition category</b> 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

**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](mailto: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 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

## 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  $\geq 20$  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 H<sub>2</sub>O 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