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Comparing non-invasive respiratory support methods following surgery in neonates with risk of extubation failure

Submission date 23/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/07/2010	**Overall study status** Completed	
Last Edited 12/07/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Does non-invasive positive pressure ventilation (NIPPV) support following surgery in neonates gives an advantage over standard oxygen/nasal continuous positive airways pressure (NCPAP) treatment in prevention of extubation failure: a multicentre randomised controlled trial

Acronym
NRSPRCT2

Study objectives
We will perform a prospective, randomised clinical trial to test the hypothesis that prophylactic application of non-invasive positive pressure ventilation (NIPPV) infants following surgery who are at high risk of reintubation will reduce extubation failure rate as compared to standard care. Standard care is defined as nasal continuous positive airways pressure (NCPAP) for infants weighing less than 2000 g and oxygen for those larger.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethical Committee of the Children's Memorial Health Institute, Warsaw, Poland, approved on the 30th October 2009 (ref: 41/KBE/2009)

Study design
Multicentre randomised unblinded controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Extubation failure in neonates

Interventions
Extubation following surgery is done according to defined criteria. Newborns above 2000 g are weaned on oxygen with fraction of inspired oxygen (FiO2) to achieve adequate peripheral oxygen saturation (SpO2), and newborns below 2000 g are weaned on NCPAP, 4 cm H2O with FiO2 to achieve adequate SpO2.

During the next 360 minutes babies are closely observed for defined risk of weaning failure. Infants with such a risk are randomised to:
1. Control arm: standard therapy - nothing is changed, or
2. Treatment arm: infant flow - NIPPV support

Treatment in both arms are continued until failure - intubation, or to time depended on individual clinical condition of the baby. The primary end point is intubation at 48 hours after extubation, the other end points are measured at 72 hours and 7 days after extubation.

The observation is closed after 7 days.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
1. Intubation at 48 hours after extubation. Weaning failure criteria as follows:
1.1. SpO2 less than 90% on FiO2 greater than 0.4, or
1.2. pH less than 7.20, or
1.3. PaCO2 greater than 65 mmHg
2. Clinical findings:
2.1. Marked increase in respiratory effort
2.2. Persistent apnea
2.3. Need for bag ventilation
2.4. Frequent apnoeas with bradycardia less than 100/min (lack of respiratory efforts for more than 20 seconds, need for stimulation greater than 3/h)
2.5. Symptoms of multiple organ failure (MOF)
2.6. Attending physician decision

Key secondary outcome(s))
1. Weaning failure at 72 hours after extubation
2. Time of oxygen and respiratory support in weaning phase
3. Complications: pulmonary (PT, PIE, atelectasis), local (skin lesions connected with prongs or tracheal tubes and apneas
4. Length of stay in the ICU and in the hospital

Completion date
30/12/2012

Eligibility

Key inclusion criteria
1. Age below 28 days or 44 weeks of corrected age
2. Birth weight greater than or equal to 1500 g
3. Surgery with general anesthesia
4. Baby is unable to wean from respiratory support in the first 6 hours after surgery
5. Parental written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Birth weight below 1500 g
2. Congenital defects making nasal prongs useless
3. Serious local (skin, nasal) lesions
4. Resuscitation, shock in last 12 hours before surgery
5. Serious central nervous system (CNS) defects or complications
6. Lethal congenital anomalies
7. Transport to other hospital in first 72 hours after surgery

Date of first enrolment
28/06/2010

Date of final enrolment
30/12/2012

Locations

Countries of recruitment
Poland

Study participating centre
Damrota 106
Tychy
Poland
43-100

Sponsor information

Organisation
The Great Orchestra of Christmas Charity (Poland)

ROR
https://ror.org/034dekp80

Funder(s)

Funder type
Charity

Funder Name
The Great Orchestra of Christmas Charity (Poland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration