

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/07/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

28/06/2010

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

Age group

Child

Sex

Both

Target number of participants

150 babies in each arm of the study (in total 300 babies)

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)

Sponsor details

ul. Niedzwiedzia 2A
Warszawa
Poland
02-737

Sponsor type

Charity

Website

<http://www.wosp.org.pl>

ROR

<https://ror.org/034dekp80>

Funder(s)**Funder type**

Charity

Funder Name

The Great Orchestra of Christmas Charity (Poland)

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