ISRCTN88744949 https://doi.org/10.1186/ISRCTN88744949

Comparison of effectiveness two Infant Flow modes (Biphasic tr vs NCPAP) in treatment infants ≤ 1250g

Submission date 06/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/08/2010	**Overall study status** Completed	
Last Edited 26/08/2010	**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

Protocol serial number
N N407 454237

Study information

Scientific Title
Comparison of effectiveness two Infant Flow modes (Biphasic tr vs NCPAP) in treatment infants ≤ 1250g. A multicentre, randomised controlled trial

Acronym
NRSPRCT3

Study objectives
To compare the efficacy and safety of treatment using two Infant Flow modes (Biphasic tr and NCPAP) in two different study groups of very low birth weight (VLBW) infants (elective to avoid intubation and weaning from mechanical ventilation after surfactant).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethical Committee of the Medical University of Silesia, Katowice, Poland, approved on the 10th July 2008 (ref: KNW/6501-114/08)

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal Diseases: Respiratory

Interventions
Newborns weighing between 500-1250g with a gestational age 32 weeks or less, will be categorised into elective or weaning study group and randomly assigned to one of the Infant Flow mode (Biphasic tr or NCPAP) in first six hours of life. Infants that meet criteria for intubation and surfactant will be assigned to the weaning arm of the study. Infants that not meet intubation criteria but required respiratory support within six hours of delivery will be enrolled in the elective arm of the study. Extubation failure in the weaning group is defined as the need for reintubation and mechanical ventilation for any reason within 72 hours of initial extubation.
Treatment failure in the elective group is defined as need for intubation in the first 3 days after first weaning from nCPAP.
Secondary endpoints include: mortality, survival without broncho-pulmonary dysplasia (BPD) or chronic lung disease (CLD), number of days on CPAP, number of days on mechanical ventilation, days on supplemental oxygen, pneumothorax, nasal complications, severe intraventricular hemorrhage, periventricular leukomalacia, retinopathy of prematurity, necrotizing enterocolitis, patient ductus arteriosus and the length of hospital stay.
The sites will be visited regularly by Study Monitors. A database of the results will be maintained by an independent data centre. The results of the study will be blinded to the Investigators, but review every 6 months by an independent Data Safety Monitoring Board according to specific criteria. Prospective power calculations indicated the need for 552 infants to be enrolled. Infants will be followed up until hospital discharge or death.

Secondary Sponsor:
The Great Orchestra of Christmas Charity (Poland)

Niedzwiedzia St. 2A
Warsaw
02-737
Poland
http://www.wosp.org.pl

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Study group A (elective):
1.1. Need for intubation within 72 hours after first weaning from nCPAP, indicated by:
1.1.1. Laboratory:
1.1.1.1. pH<7.2 AND pCO2>8,65kPa (65mmHg)
1.1.1.2. SpO2 less than 88% on FiO2 greater than 0.6
1.1.2. Clinical:
1.1.2.1. Marked increase in respiratory effort
1.1.2.2. Persistent apnea
1.1.2.3. Need for bag ventilation
1.1.2.4. 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. Study group B (weaning):
2.1. Need for intubation within 72 hours after first weaning from mechanical ventilation, indicated by:
2.1.1. Laboratory:
2.1.1.1. pH<7.2 AND pCO2>8,65kPa (65mmHg)
2.1.1.2. SpO2 less than 88% on FiO2 greater than 0.6
2.1.2. Clinical:
2.1.2.1. Marked increase in respiratory effort
2.1.2.2. Persistent apnOea
2.1.2.3. Need for bag ventilation
2.1.2.4. Frequent apnoeas with bradycardia less than 100/min (lack of respiratory efforts for more than 20 seconds, need for stimulation greater than 3/h)

Key secondary outcome(s)
1. Study group A (elective):
1.1. Total respiratory support
1.2. Duration of CPAP days
1.3. Days oxygen therapy
1.4. Length of hospital stay
1.5. Pulmonary complications (pneumothorax, interstitial emphysema, broncho-pulmonary dysplasia, chronic lung disease)
1.6. Extrapulmonary complications (intraventricular haemorrhage, periventricular leukomalacia, persistent ductus arteriosus, necrotizing enterocolitis, retinopathy of prematurity)
1.7. Local (nasal) complications

2. Study group B (weaning):
2.1. Total respiratory support
2.2. Duration of mechanical ventilation days
2.3. Duration of CPAP days
2.4. Days oxygen therapy
2.5. Length of hospital stay
2.6. Pulmonary complications (pneumothorax, interstitial emphysema, broncho-pulmonary dysplasia, chronic lung disease)
2.7. Extrapulmonary complications (intraventricular haemorrhage, periventricular leukomalacia, persistent ductus arteriosus, necrotizing enterocolitis, retinopathy of prematurity)
2.8. Local (nasal) complications

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Study group A (elective):
1.1. Preterm newborns (≤32 gestational weeks)
1.2. Birth weight 500-1250g
1.3. Any indications to intubation after birth
1.4. Signed informed consent by a parent or legal guardian

2. Study group B (weaning):
2.1. Preterm newborns (≤ 32 gestational weeks)
2.2. Birth weight 500-1250g
2.3. Clinical signs and symptoms of severe RDS
2.4. Indications into surfactant administration after delivery
2.5. Signed informed consent by a parent or legal guardian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Study group A (elective):
1.1. Preterm newborns (>32 gestational weeks)
1.2. Birth weight <500 and >1250g
1.3. Presence of congenital malformations

1.4. APGAR score < 4 (at 5min)
1.5. Incidence of air leaks
1.6. The lack of written parental consent

2. Study group B (weaning):
2.1. Preterm newborns (>32 gestational weeks)
2.2. Birth weight <500 and >1250g
2.3. Presence of congenital malformations
2.4. APGAR score < 4 (at 5min)
2.5. Incidence of air leaks
2.6. The lack of written parental consent

Date of first enrolment
15/08/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Poland

Study participating centre
Broniewskiego St. 1a/20
Katowice
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40-125

Sponsor information

Organisation
Polish Ministry of Science and Higher Education (Poland)

ROR
https://ror.org/05dwvd537

Funder(s)

Funder type
Government

Funder Name
Polish Ministry of Science and Higher Education (Poland)

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