Nasal Intermittent Positive Pressure Ventilation for Premature Infants

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Does the use of NIPPV in ELBW infants (

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON32906

Source
ToetsingOnline

Brief title
NIPPV-trial

Condition

- Neonatal respiratory disorders

Synonym
Bronchopulmonary dysplasia, Chronic Lung Disease, Respiratory Distress

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: canadian institutes of health research (CIHR): mct 80246

Intervention

Keyword: Bronchopulmonary dysplasia, Continuous positive airway pressure, Nasal

intermittent positive pressure ventilation, Preterm infants

Outcome measures

Primary outcome

composite primary outcome is BPD-free-survival. The oxygen reduction test is

used to assess BPD.

Secondary outcome

Secondary outcomes are mortality at 36 weeks, BPD at 36 weeks, other

respiratory parameters, and complications of prematurity such as NEC, ROP, IVH,

infections. Cost-effectiveness analyses.

Study description

Background summary

BPD is one of the leading causes of mortality and morbidity in ELWB infants. BPD is directly related to ventilator induced lung injury. Clinicians strive to minimize ventilator induced injury by exploring alternative non-invasive respiratory support. One important potential effective strategy is nasal intermittent positive pressure ventilation (NIPPV). Efficacy and safety of NIPPV versus standard care with continuous positive airway pressure CPAP have not been sufficiently explored yet.

Study objective

Does the use of NIPPV in ELBW infants (<30 wks of GA and BW<1000gr) requiring non-intubated respiratory support in a Level III perinatal center increase the rate of survival without BPD when compared to nCPAP.

Study design

Multicenter, international, randomised controlled, parallel, two arm trial with open label and blinded outcome assessment.

Intervention

Participating infants treated with the intention to manage the infant with non-invasive respiratory support (day 0-7) ór after extubation (day 1-28) will be randomised to non-invasive respiratory support using nasal NIPPV (study group) or nasal CPAP (control group).

Study burden and risks

Infants requiring any form of respiratory support are, by definition, requiring intensive care. Standard pressure support with nCPAP has known associated side effects: pulmonary air leaks, perforated abdominal viscera, nasal deformities and feed intolerance. We anticipate that NIPPV will carry the same complication risks. Participation to the trial does not require additional examinations or blood withdrawals, other than the oxygen reduction test (Walsh) to assess BPD. Infants randomized to the NIPPV group may have the advantage of prevention of (re)-intubation and mechanical ventilation, while CPAP alone may have failed if they were allocated to the CPAP group. On the other hand, infants randomized to the CPAP group could have the advantage of less respiratory support, that is no nasal intermittent ventilation, and more progressive weaning if CPAP alone would have been sufficient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Gestational age less than 30 weeks
Birthweight less than 1 kg
Intention to manage the infant with non-invasive respiratory support (i.e. no endotracheal tube) whether
A. primairy: within the first 7 days of life and the infant has never been intubated or has received less than 24 hours of intubated respiratory support (e.g. for endotracheal surfactant therapy /INSURE:intubate-surfactant replacement therapy-extubate)
OR
B. secondary:the infant is within the first 28 days of life, has been managed with intubated respiratory support for more than 24 hours and is a candidate for extubation followed by non-invasive respiratory support.

Exclusion criteria

1. Considered Non-viable by attending physician
2. Life-threatening congenital abnormalties including congenital heart disease (exl patent ductus arteriosus)
3. Infants known to require surgical treatmene e.g. congenital diaphragmatic hernia, tracheo-oesophageal fistula, omphalocele and gastroschisis.
4. Abnormalties of the upper and lower airways; such as Pierre-Robin sequence, Treacher Collins syndrome, Goldenhar syndrome, cleft lips and palate.
5. Neuromuscular disorders.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2010
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-06-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ISRTCN 15233270
CCMO	NL24512.042.08