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Nasal Intermittent Positive Pressure Ventilation

Submission date
28/08/2007

Recruitment status
No longer recruiting

Registration date
28/08/2007

Overall study status
Completed

Last Edited
16/08/2013

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Haresh Murli Kirpalani

Contact details
Room 3N11F, McMaster University Medical Center
1200 Main Street West
Hamilton, Ontario
Canada
L8N 3Z5
+1 905 521 2100 ext. 73024
kirpalan@mcmaster.ca

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00433212

Protocol serial number
MCT-80246

Study information

Scientific Title
Nasal ventilation in preterms (NIP) trial

Acronym
NIPPV

Study objectives
The use of nasal intermittent positive pressure ventilation (NIPPV) leads to a higher rate of survival without brochopulmonary dysplasia than standard therapy with nasal continuous positive airways pressure (nCPAP).

As of 19/08/2009 this record has been updated to include an extended anticipated end date; the initial anticipated end date of your trial was 30th April 2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was gained from Research Ethics Boards of:
1. Hamilton Health Sciences, Hamilton, Ontario, Canada on the 19th September 2006 (ref: #06-365)
2. Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada on the 11th January 2007 (ref: 06/30E)
3. Intermountain Healthcare (Institutional Review Board), Salt Lake City, Utah, USA on the 12th April 2007 (ref: # 06.2102)

Ethics approvals from other countries are pending.

Primary study design
Interventional

Study design
Multicentre, international, randomised parallel, two arm placebo trial, with outcome assessor and data analyst blinded.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bronchopulmonary dysplasia

Interventions
Experimental group: NIPPV as the sole non-ventilation respiratory support, until final weaning from all forms of respiratory support
Control group: nCPAP - nasal CPAP as the sole non-ventilation respiratory support, until final weaning from all forms of respiratory support.

Contact for public queries:
Dr. Brigitte Lemyre
Children's Hospital of Eastern Ontario (CHEO) (Canada)
401 Smyth Road
Ottawa, ON

Canada K1H 8L1
Phone: +1 613 737 8561
Fax: +1 613 737 8889

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A composite primary outcome of survival to 36 weeks gestational age, free of moderate-severe bronchopulmonary dysplasia (BPD) (i.e. major event-free survival at 36 weeks gestational age). Following the US National Institutes for Child Health and Development (NIHCHD) Consensus Statement moderate-severe BPD is defined as requiring oxygen or any respiratory support at 36 weeks age. Formal assessment for the requirement of oxygen will be conducted using the oxygen reduction test developed by Walsh.

Key secondary outcome(s)
1. All cause mortality at 36 weeks gestational age
2. All cause mortality before first discharge home
3. Bronchopulmonary dysplasia assessed at 36 weeks gestational age
4. Need for re-intubation by birth weight strata (less than 750 g; 750 g - 999 g)
5. Primary outcome per type and time of respiratory support at randomisation
6. Comparison of synchronised and non-synchronised NIPPV as a function of their effect on the primary outcome (survival at 36 weeks gestational age free of BPD)
7. Total duration of positive pressure respiratory support, i.e. mechanical ventilation plus either NIPPV or nCPAP, up to the time of discharge from the Neonatal Intensive Care Unit (NICU)
8. Total time on supplemental oxygen until discharge from NICU
9. Pulmonary air leaks identified radiologically by a masked paediatric radiologist - up to weaning off respiratory support
10. Nasal deformities: columella nasi necrosis or epistaxis
11. Intestinal perforation diagnosed by free gas in the peritoneal cavity on abdominal radiograph or at laparotomy
12. Necrotising enterocolitis, diagnosed at surgery, autopsy or by the radiographic findings of pneumatosis intestinalis or hepatobiliary gas (Bell stage II)
13. Time to establish full feeds (no longer requiring parenteral nutrition)
14. Weight gain - comparison at 36 weeks gestational age
15. Nosocomial infections, defined as positive blood culture, positive cerebrospinal fluid (CSF) culture and/or diagnosis of pneumonia

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Group A: complete obstetric and neonatal history and a clinical examination are required to confirm eligibility, however, results of study-specific laboratory or radiological investigations are not required to judge patient eligibility.
1. Gestational age at birth less than 30 weeks, either sex

2. Birthweight 999 grams or less
3. Intention to manage the infant with non-invasive respiratory support (i.e. no endotracheal tube), where either:
Group B: the infant is within the first 7 days of life and has never been intubated or has received less than 24 hours of total cumulative intubated respiratory support;
OR
Group B: the infant is within the first 28 days of life, has been managed with intubated respiratory support for 24 hours or more and is a candidate for extubation followed by non-invasive respiratory support.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Life-threatening congenital abnormalities including congenital heart disease (excluding patent ductus arteriosus)
2. Infants known to require surgical treatment, e.g. congenital diaphragmatic hernia, trache-oesophageal fistula, omphalocele, gastroschisis
3. Abnormalities of the upper and lower airways such as Pierre-Robin sequence, Treacher-Collins syndrome, Goldenhar syndrome, cleft lips and palate
4. Neuromuscular disorders

Date of first enrolment
01/09/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

Australia

Canada

Germany

Singapore

Sweden

United States of America

Study participating centre
Room 3N11F, McMaster University Medical Center
Hamilton, Ontario
Canada
L8N 3Z5

Sponsor information

Organisation
McMaster University (Canada)

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr.irsc.gc.ca (ref: MCT-80246)

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 article	results	15/08/2013		Yes	No